

Understanding the Medical Device Classification System:

*From Basics to Beyond – Using Classification to
your Competitive Advantage™*

Presented by:

Michael Drues, Ph.D.

President, Vascular Sciences
Carlsbad, California

and

Adjunct Professor of Regulatory Science, Medicine
and Biomedical Engineering

George Washington University Graduate Dept. of Regulatory Science

Cornell University Graduate Dept. of Biomedical Engineering

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For questions or more information, call
(508) 887 – 9486 or e-mail mdrues@vascularsci.com

Understanding the Medical Device Classification System:

From Basics to Beyond – Using Classification to your Competitive Advantage™

presented by: **Michael Drues, Ph.D.**

Many assume that the medical device classification system is a “no-brainer” and that classification is based simply on risk. But reality is rarely so simple. Average regulatory professionals know the rules – the best regulatory professionals know the exceptions! In this webinar, Dr. Drues uses his unique ***tell don’t ask... lead don’t follow*** approach to demonstrate how to take control of your classification strategy and most importantly to use classification to your competitive advantage.

How does one determine the class of a medical device? FDA’s classification database may help if you’re working on a me-too. But what if you’re working on something new? Or what if you want to change classification? The regulatory logic you use to make and defend your choice is critical. Many companies have experienced long and costly delays in bringing devices to market because of classification mistakes, all of which could have been easily avoided.

This webinar will give you the necessary tools to understand the classification system and more importantly to use it to your advantage! Using a case study approach, all of these questions (and others) will be answered in an interactive fashion, including:

- What is the medical device classification system?
- Why do we have a classification system? Why is it important?
- How do I determine classification?
- Can I change classification?
- How can I use classification to my advantage?
- How does labeling influence classification?
- How does risk influence classification?
- How can the same device be class 0 (wellness), class I, class II or Class III?
- How can I use classification to my advantage?
- How does classification vary in other parts of the world?
- What’s new in classification?

Participants will gain a clear understanding of device classification and learn best practices for approaching – and communicating with – the FDA. Using case studies from a variety of clinical specialties, all of these and more will be discussed in this interactive webinar. Strategies for using regulation as a competitive advantage will also be discussed.

What to know more?

Column: “Take Control Of Your Device's FDA Classification” (Med Dev Online, 7/2/14) available [here](#).

Podcast: “Who's In Control Of Your Device's Classification?” (Med Dev Online, 7/8/14) available [here](#).

For more, visit my [Guerilla Regulatory Strategy](#) column of MED Device Online magazine.

For additional information, contact Dr. Drues directly at (508) 887-9486, e-mail mdrues@vascularsci.com or via LinkedIn at www.linkedin.com/in/michaeldrues.

© Copyright 2020 by [Vascular Sciences](#). All rights reserved.

Speaker Biography



Michael Drues, Ph.D., is President of Vascular Sciences, an education, training, & consulting company offering a broad range of services to medical device, pharmaceutical & biotechnology companies including stimulating & innovative educational programing, creative regulatory strategy & complete regulatory intelligence, regulatory submission design, FDA presentation preparation & defense, brain-storming sessions, prototype design, product development, benchtop & animal testing, , clinical trial design,

reimbursement, clinical acceptance, business development & technology assessment.

Dr. Drues received his B.S., M.S., and Ph.D. degrees in Biomedical Engineering from Iowa State University in Ames, Iowa. He has worked for and consulted with leading medical device, pharmaceutical and biotechnology companies ranging in size from start-ups to Fortune 100 companies. He also works on a regular basis for the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the Centers for Medicare and Medicaid Services (CMS) and other regulatory and governmental agencies around the world.

Dr. Drues is an internationally recognized expert and featured keynote speaker on cutting-edge medical technologies and regulatory affairs. He conducts seminars and short-courses for medical device, pharmaceutical and biotechnology companies, the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the US Centers for Medicare and Medicare Services (CMS) and other regulatory and governmental agencies around the world.

Finally, as an Adjunct Professor of Regulatory Science, Medicine, Biomedical Engineering & Biotechnology, Dr. Drues teaches graduate courses in Regulatory Affairs & Clinical Trials, Clinical Trial Design, Medical Device Regulatory Affairs & Product Development, Combination Products, Pathophysiology, Medical Technology & Biotechnology at several universities & medical schools on-ground & on-line.

For a comprehensive list of columns, webinar, podcasts, etc., visit,

Global Medical Device Podcast (GreenLight.Guru) [here](#), Mike on MedTech (Medical Product Outsourcing) [here](#), Medical Design and Outsourcing [here](#), Guerilla Regulatory Strategy (MED Device Online) [here](#) and Healthcare Packaging [here](#) or LinkedIn [here](#).

Dr. Drues can be reached at:

Vascular Sciences
2105 Twain Avenue
Carlsbad, CA 92008

Phone: (508) 887-9486
Fax: (508) 861-0205
E-mail: mdrues@vascularsci.com

For additional information, contact Dr. Drues directly at (508) 887-9486, e-mail mdrues@vascularsci.com or via LinkedIn at www.linkedin.com/in/michaeldrues.

© Copyright 2020 by [Vascular Sciences](#). All rights reserved.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

Understanding the Medical Device Classification System:

From Basics to Beyond – Using Classification to your Competitive Advantage™

presented by:

Michael Drues, Ph.D.

President, Vascular Sciences, Carlsbad, California

and

Adjunct Professor of Regulatory Science, Medicine and Biomedical Engineering

George Washington University Graduate Dept. of Regulatory Science

Cornell University Graduate Dept. of Biomedical Engineering

For questions or more information, contact me at

(508) 887 – 9486 or mdrues@vascularsci.com

Join me on LinkedIn at www.linkedin.com

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

Vascular Sciences

© Copyright 2020 by Michael Drues, Ph.D.
and Vascular Sciences. All rights reserved.

Do you want more?



Jon Speer
Founder &
VP of QA/RA
Greenlight Guru

Michael
Drues, Ph.D.
President
Vascular Sciences



Global Med Dev Podcast (GreenLight.Guru) [here](#)
Mike on MedTech (Medical Product Outsourcing) [here](#)
Medical Design and Outsourcing [here](#)
Guerilla Regulatory Strategy (MED Device Online) [here](#)
Healthcare Packaging [here](#)
LinkedIn [here](#)



For columns, articles and podcasts... visit www.VascularSci.com

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

Vascular Sciences

© Copyright 2020 by Michael Drues, Ph.D.
and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mdrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
1 Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

First, an important disclaimer...



I can't make you an expert in a few minutes!

I'm not even going to try but...

Remember my philosophy of education:

To teach you how to think not what to think!

Understanding the Classification System:
Using Classification to your Advantage™

 **greenlight guru**

3

Vascular Sciences



© Copyright 2020 by Michael Druess, Ph.D.
and Vascular Sciences. All rights reserved.



Here's what we'll talk about...

- ✓ What is the medical device classification system?
- ✓ Why do we have a classification system? Why is it important?
- ✓ How do I determine classification?
- ✓ Can I change classification?
- ✓ How can I use classification to my advantage?
- ✓ How does labeling influence classification?
- ✓ How does risk influence classification?
- ✓ How can the same device be class 0 (wellness), class I, class II or Class III?
- ✓ How can I use classification to my advantage?
- ✓ How does classification vary in other parts of the world? (time permitting)
- ✓ What's new in classification?

Understanding the Classification System:
Using Classification to your Advantage™

 **greenlight guru**

4

Vascular Sciences



© Copyright 2020 by Michael Druess, Ph.D.
and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldruess,
call (508) 887-9486 or e-mail mdruess@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
2
Copyright 2020, Michael Druess, Ph.D.

Understanding the Medical Device Classification System: From Basics to Beyond – Using Classification to your Competitive Advantage™

Do you
want more?

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

5



Vascular Sciences

© Copyright 2020 by Michael Drues, Ph.D.
and Vascular Sciences. All rights reserved.

Classification: Basics and Beyond



Column: "Take Control Of Your Medical Device's FDA Classification" (Med Dev Online, July 2, 2014) available [here](#).
Podcast: "Who's In Control Of Your Medical Device's FDA Classification?" (Med Dev Online, July 8, 2014) available [here](#).

Remember three things:

Not nearly as simple as so many think!

Getting it wrong is common reason of delays and rejections

Classification can be used to your competitive advantage!

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

6

Vascular Sciences

© Copyright 2020 by Michael Drues, Ph.D.
and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mldrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
3 Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

Why is classification
important



There are many reasons!

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

7

Vascular Sciences



© Copyright 2020 by Michael Druess, Ph.D.
and Vascular Sciences. All rights reserved.

How many ways (i.e.,
pathways) are there to get
medical devices on to the
market in the United States?



Remember,

***You do not need to take the path most travelled...
unless it's to your advantage!***



Short answer:

There are many of them...

and there are advantages and disadvantages of each!

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

8

Vascular Sciences



© Copyright 2020 by Michael Druess, Ph.D.
and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldruess,
call (508) 887-9486 or e-mail mdruess@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
4 Copyright 2020, Michael Druess, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

How many ways (i.e.,
pathways) are there to get
medical devices on to the
market in the United States?



Not so short list:

1. Wellness Exemption
2. Class I Exempt / Class II Exempt
3. Pre-Market Notification a.k.a. 510k
4. De Novo
5. Pre-Market Approval (PMA)
6. Humanitarian Device Exemption (HDE)
7. Custom Device Exemption (CDE)
8. Expanded Access Pathway
9. Emergency Use Authorization (EAU)

*...and you can even mix and match!
Combination products?
Combination Regulatory Strategy*

Plus:

Breakthrough Devices Program (BDP) and Safer Technologies Program (STeP)

BDP and STeP are not pathways *per se* but certainly worth considering

Understanding the Classification System:
Using Classification to your Advantage™



9

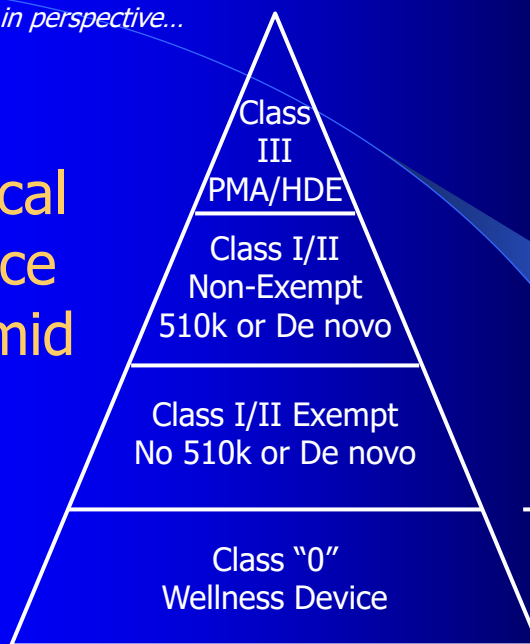
Vascular Sciences



© Copyright 2020 by Michael Druess, Ph.D.
and Vascular Sciences. All rights reserved.

Putting things in perspective...

Medical
Device
Pyramid



FDA Regulated

Not
FDA Regulated

Understanding the Classification System:
Using Classification to your Advantage™



10

Vascular Sciences



© Copyright 2020 by Michael Druess, Ph.D.
and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldruess,
call (508) 887-9486 or e-mail mdruess@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
5
Copyright 2020, Michael Druess, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

Free Live Webinar by **greenlight guru** + **VASCULAR SCIENCES**

ARE YOU SURE YOU KNOW THE BEST REGULATORY PATHWAY FOR YOUR NEW MEDICAL DEVICE?

REGISTER NOW → April 2nd @ 1:00p ET / 10:00a PT

Presenter

MICHAEL DRUES, PH.D.
President at Vascular Sciences

Moderator

JON SPEER
Founder & VP of QA/RA at Greenlight Guru

www.greenlight.guru/webinar/are-you-sure-you-know-the-best-regulatory-pathway-for-your-new-medical-device

Understanding the Classification System: Using Classification to your Advantage™ **greenlight guru** 11 **Vascular Sciences** © Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Medical Device Classification System

Question:

Why do we have a *Medical Device Classification System*?

Why is it unique to medical devices?

Why do we not have a similar system for drugs & biologics?

Should we have a similar system for drugs & biologics?

Note:

It's not sufficient to understand *what* the regulation says...

We must also understand *why* it says it in order to be able to use it to our advantage!

Understanding the Classification System: Using Classification to your Advantage™ **greenlight guru** 12 **Vascular Sciences** © Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues, call (508) 887-9486 or e-mail mdrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
6 Copyright 2020, Michael Drues, Ph.D.

From Basics to Beyond – Using Classification to your Competitive Advantage™

Why do we have a medical device classification system?

Medical devices are not all created equal



Source: US FDA CDRH 2005 Strategic Plan

Medical Device Classification System \Rightarrow Stratification of Risk

This is the theory... in reality, there are many exceptions!

Understanding the Classification System: Using Classification to your Advantage™



13

Vascular Sciences



© Copyright 2020 by Michael Druess, Ph.D.
and Vascular Sciences. All rights reserved.

How do we handle risk in medical devices



Three independent but interdependent systems:

1. Classification (Class I, Class II, Class III)
2. Non-Significant Risk (NSR) vs. Significant Risk (SR)
3. Software Classification System (Class A, Class B, Class C)

Can we make this any more complicated?

Understanding the Classification System: Using Classification to your Advantage™



14

Vascular Sciences



© Copyright 2020 by Michael Drues, Ph.D.
and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues, call (508) 887-9486 or e-mail mdrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
7 Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

Want more?

UNDERSTANDING THE MANY CONNOTATIONS OF RISK IN MEDICAL DEVICE DEVELOPMENT AND THE CONSEQUENCES OF GETTING THEM WRONG

presented by:
Michael Drues, Ph.D.
President, Vascular Sciences, Grafton, Massachusetts
Adjunct Professor of Regulatory Science, Medicine, and Biomedical Engineering
GreenLight Guru Webinar (March 23, 2017)
<http://blog.greenlightguru.com/topic/mike-drues>
For questions or more information, contact me at or
(508) 887-9486 or mdrues@vascularsci.com
Join me on LinkedIn at www.linkedin.com/in/michaeldrues

www.greenlightguru.com/webinar/many-notations-risk-medical-device-development

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

Vascular Sciences

© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Software Classification

Is my software in class A, B or C?

- ❖ Class A: No injury/damage to health is possible
- ❖ Class B: Non-SERIOUS INJURY is possible
- ❖ Class C: Death or SERIOUS INJURY is possible

Is this really so simple?

Is this really necessary?

IEC 62304:AmD1:2015 available [here](#)

```
graph TD
    Start([Class C (by default)]) --> D1{1. Can a HAZARDOUS SITUATION arise from a failure of the software?}
    D1 -- No --> A([Class A])
    D1 -- Yes --> Eval[Evaluate effectiveness of risk CONTROL measures external to the software]
    Eval --> D2{2. Does failure of the software result in unacceptable RISK?}
    D2 -- No --> A
    D2 -- Yes --> D3{3. What severity of injury is possible?}
    D3 -- Non SERIOUS INJURY --> B([Class B])
    D3 -- SERIOUS INJURY/death --> C([Class C])
```

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

Vascular Sciences

© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

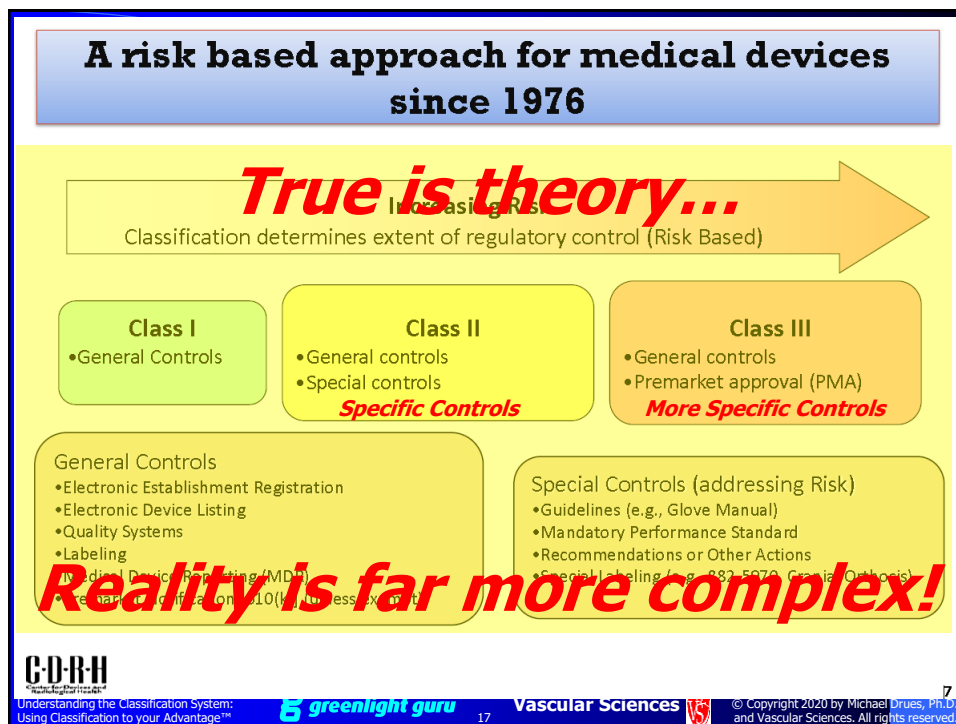
GreenLight.Guru Webinar (July 16, 2020)

www.greenlightguru.com/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mdrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
8 Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: From Basics to Beyond – Using Classification to your Competitive Advantage™



Medical Device Classification System

	Description	Examples
Class I	<ul style="list-style-type: none"> Present minimal harm to user Typically simple in design History of safe use 	<ul style="list-style-type: none"> Tongue depressors Compression hosiery Hand-held surgical instruments
Class II	<ul style="list-style-type: none"> General controls are not sufficient to ensure safety Guidance documents available to provide safe and effective usage 	<ul style="list-style-type: none"> Physiologic monitors X-ray systems Powered wheelchairs Surgical drapes
Class III	<ul style="list-style-type: none"> Support or sustain human life Have substantial importance in preventing impaired health May present a risk of illness or injury 	<ul style="list-style-type: none"> Replacement heart valves Components of joint replacements Silicone breast implants Implanted cerebella stimulators

Source: FDA

Table 1. Device classification defines the regulatory requirements for a general device type.

taken from "Medical Device Trials" (Applied Clinical Trials, May, 2012)

...or so the theory goes, there are loads of exceptions!

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

Vascular Sciences

© Copyright 2020 by Michael Druess, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

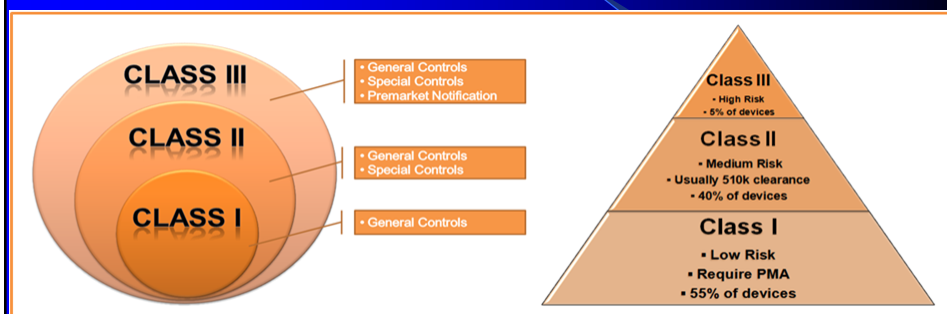
www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldruess,
call (508) 887-9486 or e-mail mdruess@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
9 Copyright 2020, Michael Druess, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

There are mistake(s) on this slide... can you find them?



Center for Emerging Neurotechnologies, University of Cincinnati

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

19

Vascular Sciences



© Copyright 2020 by Michael Drues, Ph.D.
and Vascular Sciences. All rights reserved.

Is a hospital bed a
medical device?



And if so, what class is it?

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

20

Vascular Sciences



© Copyright 2020 by Michael Drues, Ph.D.
and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mdrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
10
Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: From Basics to Beyond – Using Classification to your Competitive Advantage™

Is a hospital bed a medical device?

OnlineTMD.com
November/December 2009

Today's Medical Developments

TMD

**INTELLIGENT
HOSPITAL BEDS**

Brush Research Mig's
Diamond Hone Flex Tools

Foster Corp's Radiopaque
Polymer Enhancement

Mori Seiki's MAPPS IV
Operating System

Once a simple application,
hospital beds have evolved
into a **Class 2 medical device**
with significant intelligence.

Today's Medical Developments, November/December, 2009
© Copyright 2020 by Michael Drues, Ph.D.
and Vascular Sciences. All rights reserved.

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

21

Vascular Sciences

Hospital Beds

Health Canada Santé Canada

GUIDANCE DOCUMENT
Adult Hospital Beds: Patient Entrapment Hazards, Side
Rail Latching Reliability, and Other Hazards

Published by authority of the
Minister of Health

Date Adopted	2006/12/20
Revised Date	2008/02/28
Effective Date	2008/03/17

Health Products and Food Branch

Canada

Adult Hospital Beds: Patient Entrapment Hazards, Side Rail
Latching Reliability, and Other Hazards
(Health Canada, March 17, 2008) available [here](#).

Bed-related Entrapment and Fall Report Form →
(Health Canada, March 17, 2008) available [here](#).

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

22

Vascular Sciences

25. If an entrapment event occurred, indicate the location of entrapment by
circling the appropriate Zone number.

Potential Entrapment (Zones 1, 2, 3 and 4 are the only zones assessed.)

Zone 1 - Entrapment within rail

Zone 2 - Entrapment between top of compressed mattress to bottom of rail, between rail and supports

Zone 3 - Entrapment in horizontal space between rail and mattress

Zone 4 - Entrapment between top of compressed mattress and bottom of rail at end of rail

Good example of a customer complaint form because...

very simple

easy to understand (pictures)

quick to fill out (only 10 pages?)

contains all relevant info

users more likely to fill it out

on-line version could be created

several quantifiable variables → easily integrate/track in QMS

Bed-related Entrapment and Fall Report Form 6 March 2008

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

23

Vascular Sciences

and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mldrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
11
Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

How about a 'regular' bed?



Don't think so...
listen to the claims.

Where are they on the
labeling continuum?
What is their *regulatory risk?*

One of my favorite regulatory strategies is based on the adage...

Better to ask forgiveness than permission!

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

23

Vascular Sciences



© Copyright 2020 by Michael Drues, Ph.D.
and Vascular Sciences. All rights reserved.

The Medical Device "Slippery Slope"

So... if a hospital bed is a medical device, let's take this a step further:

Suppose your company manufactured the wheels of the bed. You sell the same wheels to many companies who in turn use your wheels in many different types of products and industries. But because one of your customers is attaching your wheels to a hospital bed which is regulated as a medical device, does that mean you now become a medical device manufacturer?

Now suppose you work for a company that makes the rubber that goes into the wheels that attach to the hospital bed, does your rubber company now become a medical device manufacturer.

Now suppose you work for a company that makes the solvent in the rubber that goes into the wheels that attach to the hospital bed, does your solvent company now become a medical device manufacturer. And so on and so on and so on...

Some might think this is a facetious argument. Perhaps so but remember this example when we discuss the "breast implant fiasco" and specifically the impact on biomaterial manufacturers.

Class II medical devices are typically non-invasive and include x-ray machines, picture archiving and communication systems (PACS), powered wheelchairs, infusion pumps, surgical drapes, surgical needles and suture material and acupuncture needles. In fact, **43% of medical devices fall under this category. But pacing leads are also regulated as class II devices.** So is a hospital bed equivalent to a pacing lead? More on that later...

How about an example?

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

24

Vascular Sciences



© Copyright 2020 by Michael Drues, Ph.D.
and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

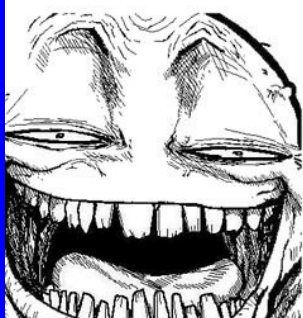
For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mdrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
12
Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: From Basics to Beyond – Using Classification to your Competitive Advantage™

Think I'm joking?

You laugh 'cause you think I'm kidding,
I laugh 'cause I know I'm not.



Let's see why...

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru


25

Vascular Sciences

© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

So if a hospital bed is a medical device...

Are bed rails medical devices?



- ✓ Between 2003–2012, >150 adults died and 36K mostly elderly adults were injured after becoming trapped in bed rails. FDA said data probably understates problem since bed rails are not always listed as a cause of death by nursing homes/coroners/ER doctors. Experts say **the deaths are avoidable**. But remember, many deaths are avoidable!
- ✓ Both [FDA & Consumer Product Safety Commission] had known about deaths/injuries for more than a decade but had done little to crack down on the companies that make them. Why?
- ✓ Are [bed rails] medical devices under FDA or consumer products regulated by CPSC? There are hundreds of bed rails sold at medical supply stores/discount retailers which **may or may not be considered medical devices, depending on whether the manufacturer makes specific claims, i.e., the device will keep a dementia or Alzheimer's patient from falling out of bed. Without such claims, it may be viewed as a consumer product.** As a manufacturer, how would you avoid this?
- ✓ Forcing industry to improve designs and replace older models could cost bed rail makers and health care facilities hundreds of millions of dollars. *None of bed rails in use would have passed suggested design standards proposed in 1995 if they were mandatory.*

What is safety? How safe is safe? Where do we draw the line? And... at what cost?

Understanding the Classification System:
Using Classification to your Advantage™

New York Times, November 25, 2012 and USA Today, Dec. 5, 2012

greenlight guru

26

Vascular Sciences

© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)


www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mdrues@vascularsci.com


Taken from: *Designing Medical Products Seminar Series*
13
Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: From Basics to Beyond – Using Classification to your Competitive Advantage™


What is a medical device?




Is a 'go kart' a medical device?



How about an ambulance?



Is a wheelchair a medical device?
How about a wheelchair cushion?



Don't think so, then how do you explain this?

[Unapproved Wheelchair Cushions Top Multi-Issue Warning Letter](#)

"A Tennessee maker of wheelchair components received an FDA warning letter after the agency determined some products advertised on the company's website had never been formally approved. The letter cited AireRx Healthcare with nine violations, including the company's online promotion of wheelchair cushions described as reducing causes of skin tissue trauma. The product was never cleared via PMA or investigational device exemption, which is required for wheelchair components carrying specific health claims."

[Devices & Diagnostics Letter (Aug 20, 2012)]

Why did this happen? Could it have been avoided?

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru Warning Letters **Vascular Sciences**

© Copyright 2020 by Michael Druess, Ph.D. and Vascular Sciences. All rights reserved.

Back to registration...

Who needs to be FDA Registered and who does not?

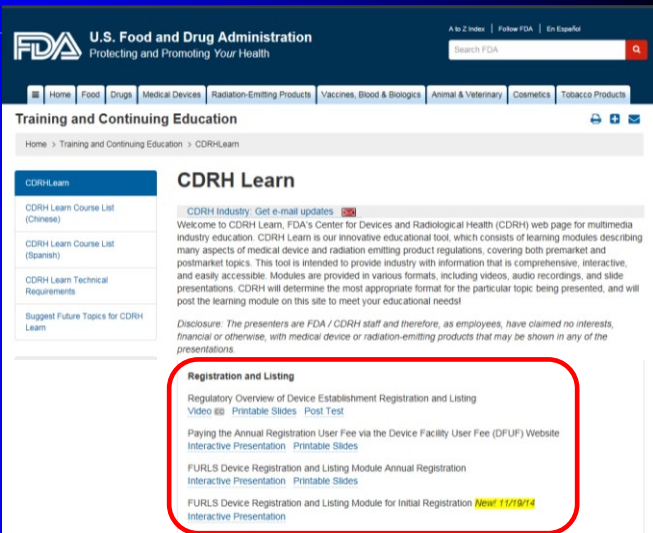
Bottom line:

Not a simple decision

It's not simply a regulatory or legal decision, it's a business decision!

There are advantages and disadvantages to being registered and not!

Want more? Check out these podcasts



www.fda.gov/Training/CDRHLearn/
[11/19/14]

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru **Vascular Sciences**

© Copyright 2020 by Michael Druess, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldruess,
call (508) 887-9486 or e-mail mdruess@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
14 Copyright 2020, Michael Druess, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

How do I determine the classification of my device



Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

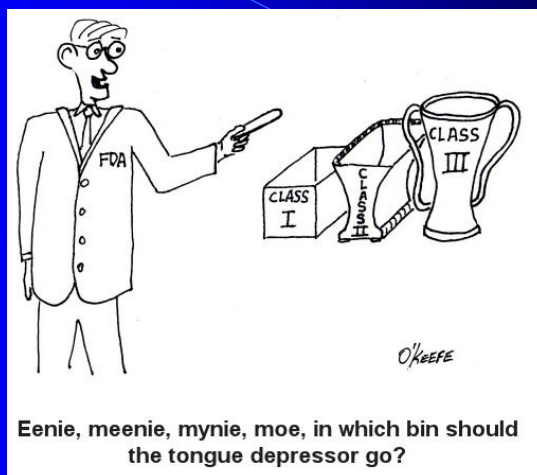
29

Vascular Sciences



© Copyright 2020 by Michael Drues, Ph.D.
and Vascular Sciences. All rights reserved.

How do I determine the classification of my device?



www.engineeringexpert.net

Bottom line:

Not nearly as simple as many think!

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

30

Vascular Sciences



© Copyright 2020 by Michael Drues, Ph.D.
and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mdrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
15
Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: From Basics to Beyond – Using Classification to your Competitive Advantage™

How do I determine the classification of my device?

First question:



CDRH Website (April, 2014) [here]

Assuming it's a regulated medical device, next question:

What is the classification, i.e., how is classification determined?

Short answer:

It depends!

What does it depend on?

Is it an existing device? *vs.* Is it a new device?

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

31

Vascular Sciences

© Copyright 2020 by Michael Druess, Ph.D.
and Vascular Sciences. All rights reserved.

Is a ringtone a medical device?



The answer may not be as simple as you think!

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

32

Vascular Sciences

© Copyright 2020 by Michael Druess, Ph.D.
and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldruess,
call (508) 887-9486 or e-mail mdruess@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
16
Copyright 2020, Michael Druess, Ph.D.

Understanding the Medical Device Classification System: From Basics to Beyond – Using Classification to your Competitive Advantage™

Thinking beyond phones and apps...

Is a ringtone a medical device?



Don't think so... not so fast!



How about a ringtone that tells you you're having a heart attack? Not possible?
Think again!

So if a heart attack ringtone is a medical device... what class is it?
Hint: *what's the risk?*

Understanding the Classification System:
Using Classification to your Advantage™


greenlight guru

33

Vascular Sciences

© Copyright 2020 by Michael Druess, Ph.D. and Vascular Sciences. All rights reserved.

What class should this app be?



Background:

- 3-lead wireless ECG, prescribed by doctor, worn continuously under patient's clothing
- continuously sends ECG readings to smartphone via Bluetooth and to physician
- device will send clinician an alarm when it detects irregular heartbeat (i.e., arrhythmia) – physician can review data and send email to patient
- if patient uses additional Bluetooth devices (i.e., BP monitor), app can display that data as well
- user can enable a GPS feature in app so first responders can find them in emergency

MobileHealthNews, Dec. 5, 2013

510(k) Premarket Notification

FDA Home | Medical Devices | Databases

510(k) | Registration & Listing | Adverse Events | recalls | PMA | Classification | Standards | Inspections
QIR Title 21 | Radiation-Emitting Products | 3rd Party Issuance | Market Reports | CDR | TPLC

New Search [Back To Search Results](#)

Device Classification Name	Transmitters And Receivers, Electrocardiograph, Telephone
510(k) Number	K131999
Device Name	EMOTION ECG MOBILE
Original Applicant	MEGA ELECTRONICS LTD. Proteusgracht 20 The Hague, Andre Kinkorster
Original Contact	Andre Kinkorster
Regulation Number	823.2502
Classification Product Code	0203
Date Received	06/11/2013
Decision Date	11/29/2013
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Cardiovascular
Review Advisory Committee	Cardiovascular
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No
Combination Product	No

How should this EKG app be regulated?

Class I, II, III? maybe not regulated at all?
510k? PMA? Something else?

510k Class II

More importantly,
Why, i.e., what is the regulatory logic?

Hint:
Substantial Equivalence or Risk

Dec. 5, 2013

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

34

Vascular Sciences

© Copyright 2020 by Michael Druess, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldruess,
call (508) 887-9486 or e-mail mdruess@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
17
Copyright 2020, Michael Druess, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

Peace of mind in your pocket.

Take control of your heart health with the help of your smartphone or tablet.



Compatible with most Apple or Android devices.

Case Study: Kardia Mobile



Could this be a wellness device?

INDICATIONS FOR USE

The AliveCor Heart Monitor is **intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms**. The AliveCor Heart Monitor **also displays ECG rhythms and detects the presence of atrial fibrillation** (when prescribed or used under the care of a physician). The AliveCor Heart Monitor is intended for use by healthcare professionals, patients with known or suspected heart conditions and **health conscious individuals.**

[K140933](#) / Product Code [DXH](#) / 510k Summary [here](#)

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

35

Vascular Sciences

© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

What's a different way to get an EKG App to market?



Veterinary Indication → Human Indication
Usually happens the other way around... how?
Twist on a label expansion... or rather species expansion! 😊
Don't we often do 'animal studies' anyway? So is this really any different?
Hint: An animal study without the 'study' – a.k.a. post market surveillance (PMS ≠ Phase IV)

facebook



EASIER VETERINARY ECG SCREENING IS HERE.

AliveCor Vet Product/Service

Why not advertise on Facebook?

Think about the sales process:

I use this on my dog... now I want to use it on me?

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

36

Vascular Sciences

© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mdrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
18
Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

When could the same technology not be a medical device?



How about using your heartbeat as
your password?

Watch this...

So it's not about what
your device *can* do...
rather it's about *how you*
use the information and
what you say it does!



PUT YOUR
HEART INTO IT

SAY GOODBYE TO
PASSWORDS, PINS, AND
EVEN KEYS AND CARDS.

Understanding the Classification System:
Using Classification to your Advantage™

 greenlight guru

37

Vascular Sciences



© Copyright 2020 by Michael Druess, Ph.D.
and Vascular Sciences. All rights reserved.

What if we raise the 'risk'



Understanding the Classification System:
Using Classification to your Advantage™

 greenlight guru

38

Vascular Sciences



© Copyright 2020 by Michael Druess, Ph.D.
and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)


www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldruess,
call (508) 887-9486 or e-mail mdruess@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
19 Copyright 2020, Michael Druess, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

Case Study: *DIY Arrhythmia Diagnosis?*



First, what's an arrhythmia, i.e., atrial fibrillation?

AliveCor Receives First FDA Clearance to Detect Serious Heart Condition on a Mobile Device

FDA granted clearance for algorithm to detect atrial fibrillation (A-Fib), most common form of cardiac arrhythmia via mobile phone so physicians can intervene before potentially life-threatening conditions (i.e., ischemic stroke) occur

Stats:

- 1 in 4 adults >40 develop A-Fib → ↑5X ischemic stroke
- A-Fib hard to detect (symptoms, i.e., heart palpitations, may be mild or non-existent)
- **Platform technology:** develop other algorithms for diagnosing other arrhythmias



Indication for Use: AliveCor Heart Monitor is intended to record, display, store and transfer electrocardiogram (ECG), detects presence of atrial fibrillation (when prescribed by physician) in patients with known or suspected heart conditions and health conscious individuals.

summarized from EP Lab Digest (September, 2014)

Why 510k?

Hint: Substantial Equivalence Argument + Risk Mitigation Strategy → ↑ Success (↓ Regulatory Risk)

Understanding the Classification System:
Using Classification to your Advantage™

39

© Copyright 2020 by Michael Druess, Ph.D. and Vascular Sciences. All rights reserved.

Don't just consider what we're doing... consider what we're not doing and ask why are we not doing it?

Consider these scenario's:



- we have the technology today via software, artificial intelligence, etc. to allow an ECG monitor not simply to display the ECG waveform but to then make a clinical diagnosis of an arrhythmia, i.e., atrial fibrillation, bundle branch block, etc. and to go further to prescribe treatment, i.e., put the patient on drug X at dosage Y, etc. In fact, I've helped 2 companies do exactly that.
- a BP monitor provides your blood pressure as numerical values, i.e., 120/80 mmHg. It does not provide a clinical diagnosis, i.e., it does not tell you that you have hypertension, nor does it tell you what drug(s) to take. Why not?
- an x-ray machine provides an image of a broken bone, but it does not say you have a broken bone i.e., does not perform a clinical diagnosis, nor does it tell you how to treat it. Why not?
- and so on and so on...

All of the above are easy to do from a technology perspective, but most companies do not want to do these things. Why not? Note: the answer is the same for each!

Hint: it's mostly for regulatory reasons and not engineering reasons.

Who can explain?

Understanding the Classification System:
Using Classification to your Advantage™

40

© Copyright 2020 by Michael Druess, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)


www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldruess,
call (508) 887-9486 or e-mail mdruess@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
20
Copyright 2020, Michael Druess, Ph.D.

Understanding the Medical Device Classification System: From Basics to Beyond – Using Classification to your Competitive Advantage™

What is the classification of a scalpel




Class 0 ?

Class I ?


Class II ?


Class III ?

It depends



Understanding the Classification System:
Using Classification to your Advantage™


41

Vascular Sciences

© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Where to begin?

Classification depends on 3 things:

- intended use & indications for use
- risk [many connotations!]
 - to patient & to user
 - using device
 - not using device
 - wrong information
 - regulatory risk
 - many others...

Not nearly so simple!

Example: *What class is a scalpel?*

Short answer: *it depends!*

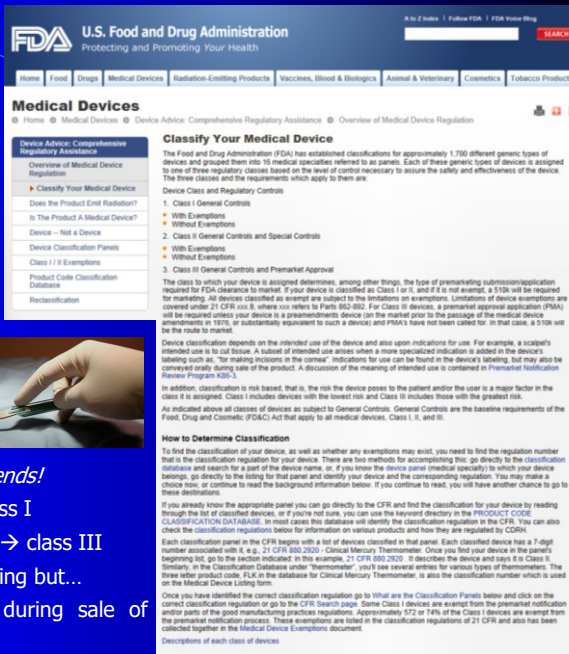
intended use → cut tissue → class I

intended use → corneal incision → class III


indications for use found in labeling but...


may also be conveyed orally during sale of product so...

Should you put this 'use' on your label?



Understanding the Classification System:
Using Classification to your Advantage™


42

Vascular Sciences

CDRH Website (April, 2014) [here]
© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mldrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
21 Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*




Effective Communication

*It's not what you say...
it's what people hear!*

Dr. Frank Luntz (January, 2007)



Understanding the Classification System:
Using Classification to your Advantage™

 43  © Copyright 2020 by Michael Druess, Ph.D. and Vascular Sciences. All rights reserved.



Zona Plus

Understanding the Classification System:
Using Classification to your Advantage™

 44  © Copyright 2020 by Michael Druess, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system


For additional information, www.linkedin.com/in/michaeldruess,
call (508) 887-9486 or e-mail mdruess@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
22 Copyright 2020, Michael Druess, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

2 min ad [here](#) / 1 min ad [here](#)

Case Study: Zona Plus



How would you bring this device to market?

- Wellness Device? ("Class 0")
- Class I Exempt?
- Class II Exempt?
- Class II Non-Exempt (510k or De novo)
- Class III (PMA or HDE)
- Something else?

More importantly... **Why? What's the regulatory logic?**

Short answer:

It depends... so what does it depend on?

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

45

Vascular Sciences

© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Case Study: Zona Plus

Note the claim:



INTRODUCING THE 'ZONA PLUS: SERIES 3'

The Zona Plus is different from anything you've seen before. It is the world's first handheld device which is used to aid in the improvement of cardiovascular health.

www.zona.com

Why is this important?

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

46

Vascular Sciences

© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)


www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mdrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
23
Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

Case Study: Zona Plus



Here is the answer:

zona HEALTH™ The Power to Change™

DEVICE SCIENCE REALSTORIES 1-800-252-3810 BUY NOW

IS THE ZONA PLUS FDA-APPROVED?

The Zona Plus is in a category of medical devices that do not require FDA approval. The Zona Plus does have to be listed by the FDA for quality control purposes, and this listing is current.

www.zona.com

What does this mean?

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru 47 **Vascular Sciences**

© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Case Study: Zona Plus



Establishment Registration & Device Listing

FDA Home Medical Devices Databases

New Search Back To Search Results

Proprietary Name:	CARDIOGRIP; ZONA PLUS
Classification Name:	EXERCISER, POWERED
Product Code:	BXB
Device Class:	1
Regulation Number:	890.3380
Medical Specialty:	Physical Medicine
Registered Establishment Name:	Zona Health, Inc.
Registered Establishment Number:	3005404127
Owner/Operator:	Zona Health, Inc.
Owner/Operator Number:	9077483
Establishment Operations:	Manufacturer; U.S. Manufacturer of Export Only Devices; Complaint File Establishment

Establishment Registration available [here](#).

What is product code BXB...

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru 48 **Vascular Sciences**

© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)


www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mdrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
24 Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: From Basics to Beyond – Using Classification to your Competitive Advantage™

Case Study: Zona Plus



Product Classification
FDA Home Medical Devices Databases

New Search Back to Search Results

Device	Exerciser, Powered
Regulation Description	Powered exercise equipment.
Regulation Medical Specialty	Physical Medicine
Review Panel	Physical Medicine
Product Code	BXB
Premarket Review	Office of Device Evaluation (ODE) Division of Neurological and Physical Medicine Devices (DNPM) Physical Medicine and Rehabilitation Devices Branch (PMDB)
Submission Type	510(K) Exempt
Regulation Number	890.5380
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible

Why is this device Class I Exempt?


Note: FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the Federal Registers of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status of a device. For example, Class I devices that are exempted from the premarket notification requirement are not exempted from the requirements of 21 CFR Parts 802-892, a premarket notification application and FDA clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the [Device Registration and Listing website](#) for additional information.

Implanted Device? No
Life-Sustain/Support Device? No
Third Party Review Not Third Party Eligible

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru 49 Vascular Sciences Product Code BXB available here © Copyright 2020 by Michael Druess, Ph.D. and Vascular Sciences. All rights reserved.

Case Study: Zona Plus



Is Class I Exempt the only correct answer? Could it be something else?

zонаHEALTH™ The Power to Change™

DEVICE SCIENCE REAL STORIES 1-800-252-3810 BUY NOW

IS THE ZONA PLUS FDA-APPROVED?

The Zona Plus is in a category of medical devices that do not require FDA approval. The Zona Plus does have to be listed by the FDA for quality control purposes, and this listing is current.

Choices: Wellness Device? 510k? De novo? PMA?

Absolutely Not!

Hint: Nothing in the regulatory world is black and white!

Question:

Can you make this a wellness device? 510k? De novo? PMA?

Hint: What if you change the claims?

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru 50 Vascular Sciences © Copyright 2020 by Michael Druess, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldruess,
call (508) 887-9486 or e-mail mdruess@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
25 Copyright 2020, Michael Druess, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

What is the classification of a video game?



Can a video game be a regulated medical device?

Understanding the Classification System:
Using Classification to your Advantage™

 greenlight guru

51

Vascular Sciences



© Copyright 2020 by Michael Drues, Ph.D.
and Vascular Sciences. All rights reserved.

Case Study: EndeavorRx Video Game for ADHD



EndeavorRx Trailer (30 sec) [here](#)

EndeavorRx (DEN200026)
FDA Press release [here](#)
Product website [here](#)

INSIGHT™
ADHD
our behavior tracking app

U.S. FOOD & DRUG ADMINISTRATION	
Device Classification Under Section 513(f)(2)(De Novo)	
New Search	
De Novo Number	DEN200026
Device Name	EndeavorRx
Requester	AAB Interactive Labs Inc. 125 Broad Street, 4th Floor Boston, MA 02110 Scott Kellogg
Contact	
Classification Product Code	CFT
Date Received	04/16/2020
Decision Date	06/15/2020
Decision	Granted (DEN2)
Review Advisory Committee	Neurology
Reclassification Order	Reclassification Order
Type	Direct

"The first game-based therapeutic granted marketing authorization by the FDA for any type of condition. Available to patients without a prescription in April under FDA's enforcement discretion policy for digital health devices for treating psychiatric disorders during the coronavirus disease (COVID-19) public health emergency."

First video game-based treatment gets go ahead from FDA (RAPS, June, 2020) [here](#)

Understanding the Classification System:
Using Classification to your Advantage™

 greenlight guru

52

Vascular Sciences



© Copyright 2020 by Michael Drues, Ph.D.
and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mdrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
26
Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

What is the classification
of a refrigerator?



Can a refrigerator be a regulated medical device?

Understanding the Classification System:
Using Classification to your Advantage™



53

Vascular Sciences



© Copyright 2020 by Michael Drues, Ph.D.
and Vascular Sciences. All rights reserved.

Case Study: Refrigerator



Is a refrigerator a medical device?

Could it depend on what you put in it?



Could you store blood in your refrigerator at
home?

Absolutely... but that would be off-label use!

Understanding the Classification System:
Using Classification to your Advantage™



54

Vascular Sciences



© Copyright 2020 by Michael Drues, Ph.D.
and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mdrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
27
Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: From Basics to Beyond – Using Classification to your Competitive Advantage™

New Search
Back to Search Results

Device	Refrigerator, Freezer, Blood Storage
Regulation Description	Blood storage refrigerator and blood storage freezer.
Regulation Medical Specialty	Hematology
Review Panel	Hematology
Product Code	KSE
Premarket Review	Center for Biologics Evaluation & Research (CBER)
Submission Type	510(K) Exempt
Regulation Number	864.9700
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Multifunction Reporting	Eligible

Note: Class II devices the Food and Drug Administration (FDA) has also published a [list of class II \(special controls\) devices](#) subject to certain limitations, that are exempt from premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (FDAMA) and the 21st Century Cures Act of 2016 (Cures Act). FDA believes that these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues. FDA is taking this action in order to meet requirements of FDAMA and the Cures Act.

Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

Product code: **KSE / 864.9700** Class II 510k Exempt

Vascular Sciences

© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

New Search
Help | More About 21CFR

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2019]
[CITE: 21CFR864.9700]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 864 -- HEMATOLOGY AND PATHOLOGY DEVICES

Subpart J--Products Used In Establishments That Manufacture Blood and Blood Products

Sec. 864.9700 Blood storage refrigerator and blood storage freezer.

(a) *Identification.* A blood storage refrigerator and a blood storage freezer are devices intended for medical purposes that are used to preserve blood and blood products by storing them at cold or freezing temperatures.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 864.9.

[45 FR 60650, Sept. 12, 1980, as amended at 63 FR 59226, Nov. 3, 1998]

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

Product code: **KSE / 864.9700** Class II 510k Exempt

Vascular Sciences

© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mdrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
28
Copyright 2020, Michael Drues, Ph.D.


Understanding the Medical Device Classification System: From Basics to Beyond – Using Classification to your Competitive Advantage™

Why class II? Why 510k exempt?

39 KSE 510k's here (1980-1999)

Understanding the Classification System:
Using Classification to your Advantage™


57



Vascular Sciences and Vascular Sciences. All rights reserved.

What can happen when you get classification wrong

Sometimes it can be an expensive lesson learned!



Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

Vascular Sciences

© Copyright 2020 by Michael Drues, Ph.D.
and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mdrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
29 Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

Reality is rarely as simple as many think!

Case Study: Willow Curve



What's the regulatory strategy...
not necessarily the regulatory pathway?
[Note: regulatory strategy ≠ regulatory pathway!]
What is the 'regulatory' risk?

Willow Curve Knee Pain Device Ad (1 min) available [here](#).

Understanding the Classification System:
Using Classification to your Advantage™

 59  © Copyright 2020 by Michael Druess, Ph.D.
and Vascular Sciences. All rights reserved.



Advanced Laser Therapy

Willow Curve is a revolutionary, portable medical device that intelligently applies a painless, noninvasive low level laser therapy (LLLT) to the treatment area. LLLT has been clinically proven to have an analgesic effect as well as provide improved circulation that promotes detoxification, reduces inflammation and swelling, and kickstarts the body's natural healing processes. Willow Curve treatments have no side effects.

Case Study: Willow Curve

Willow Labs and its marketers **will stop making claims that its light therapy device**, the Willow Curve, **treats chronic, severe pain and associated inflammation, under a \$22 million settlement** with the Federal Trade Commission (FTC).

The FTC alleged that the marketers **promoted the device nationwide as a "smart" device that is "clinically proven," even though they lacked scientific evidence to support the claims.**


They also **falsely claimed that** Willow Curve, a curved device that emits infrared and invisible light, **was approved by the FDA to diagnose and treat chronic, severe pain and reduce inflammation**, according to the FTC.

Take away:

Both FDA and FTC are cracking down on wellness devices with unsubstantiated claims
You can say whatever you want about your product... as long as you can prove it!

Willow Labs Settles False Advertising Claims for \$22 Million (July 16, 2020) [here](#) / Company website [here](#)

Understanding the Classification System:
Using Classification to your Advantage™

 60  © Copyright 2020 by Michael Druess, Ph.D.
and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldruess,
call (508) 887-9486 or e-mail mdruess@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
30
Copyright 2020, Michael Druess, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

What can happen when you overplay your hand?

CALL US NOW AT (888) 752-1280 | SHOP WITH ALL MAJOR CREDIT CARDS OR YOUR FLEX SPENDING/HSR CARD

WILLOW Curve

HOME SHOP THE CURVE INVESTORS GUIDES PARTNER WITH WILLOW USD

We have Temporarily Suspended Shipping the Willow Curve.

Please check back with us. We wish you and your family all the best. Please stay safe. Questions? Please email us at support@willowmd.com

www.willowcurve.com (July 15, 2020)

Understanding the Classification System: Using Classification to your Advantage™

greenlight guru 61 Vascular Sciences

© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

How could this have been avoided?

Easy!

Claims directly proportional to Class

Want to be Class I Exempt? → Make weak claims.

Want to make stronger claims? → Go up in class.

Most important:

Regardless of class... make sure you can support your claims!

Note: FDA may be interested in class... FTC could care less!

Understanding the Classification System: Using Classification to your Advantage™

greenlight guru 62 Vascular Sciences

© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mdrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
31 Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

Regulatory Strategy Pyramid

The best regulatory professionals know how to take advantage of what they don't say!
Even greater regulatory professionals know how not to say it.
Great regulatory professionals know what not to say...
Better regulatory professionals know how to say it.
Good regulatory professionals know what to say...



The higher you go, the fewer there are... what does that tell you?

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

63

Vascular Sciences

© Copyright 2020 by Michael Druess, Ph.D.
and Vascular Sciences. All rights reserved.

Another Classification Example

Is a dental light a *regulated* medical device? If so, what class?

Short answer:

It depends!

On what?

Indication!

if indication_{Daylight} [21CFR872.4620] OR if indication_{Bleaching} [21CFR872.6420] → Class 1 Exempt

but if indication_{Curing} [21CFR872.6070] → Class 2 (510k)

even though wavelength of light (i.e., dosage) is exactly the same!

Why? Hint: Think risk... but what connotation of risk?

And in the EU?

Rule 12 - All other active devices

General explanation of the rule

This is a fallback rule to cover all active devices not covered by the previous rules.

RULE 12

All other active devices are in Class I

EXAMPLES

- Active diagnostic devices intended to illuminate the patient's body in the visible spectrum such as examination lights or to optically view the body such as surgical microscopes
- Devices intended in general for external patient support (e.g. hospital beds, patient hoists, wheelchairs, dental patient chairs)
- Active diagnostic devices intended for thermography
- Dental curing lights

Classification of Medical Devices (EC, June, 2010) (p.45)

Understanding the Classification System:
Using Classification to your Advantage™

Does someone have to much time on their hands?

64

Vascular Sciences

© Copyright 2020 by Michael Druess, Ph.D.
and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldruess,
call (508) 887-9486 or e-mail mdruess@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
32
Copyright 2020, Michael Druess, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

Device Classification Database



Databases can be used for many things...


Great for competitive intelligence as well!

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpdc/classification.cfm>

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru 65 **Vascular Sciences** © Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Can classification be changed and if so by whom?



Short answer: *Yes!*

By FDA and by you (but not unilaterally)

Down-Classification vs. Up-Classification

Note: regulatory logic same as drugs!

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru 66 **Vascular Sciences** © Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mdrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
33 Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: From Basics to Beyond – Using Classification to your Competitive Advantage™

Reclassification Petition

What should be included?



Sec. 860.123 Reclassification Petition: Content and form.

Any petition for reclassification of a device shall include:


1. specification of **type of device** for which reclassification is requested;
2. statement of action, e.g., "It is requested that XXX device(s) be reclassified from class III to a class II";
3. supplemental data sheet applicable to device for which reclassification is requested;
4. classification questionnaire applicable to device for which reclassification is requested;
5. statement of basis for disagreement with an existing classification decision;
6. full statement or reasons, with supporting data, why device should not be classified into present classification and how proposed classification will provide **reasonable** assurance of safety and effectiveness of device;
7. representative data/information known by petitioner that are unfavorable to petitioner's position;
8. if petition is based upon new information, a summary of new information;
9. source documents from which new information used to support the petition has been obtained.
10. financial certification or disclosure statement or both.

edited from CDRH website (July, 2014) available [here](#)



Understanding the Classification System:
Using Classification to your Advantage™

 69  © Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

What if your device has not been classified



Understanding the Classification System:
Using Classification to your Advantage™

 70  © Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mdrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
35 Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: From Basics to Beyond – Using Classification to your Competitive Advantage™

Request for Information

- Also known as the 513(g) but remember...
This is a process not a form!
- FDA has 60 days to respond (in theory)
- Note: User fees apply!

"Typical" 513(g) inquiries to date:

- Is device subject to FDA regulation?
- Is device exempt from 510(k) requirements (Class 0)?
- Does modification of existing marketed device require new 510(k)? [i.e., 'special' 510(k)]
- If new device introduces new technology/new intended use, what is regulatory pathway?

See CDRH on-line presentation [here](#) for more.

What about a
Request for RE-Classification?
FDA does it (occasionally)... you can to!

Procedures for Section 513(g) Requests for Information (FDA, April, 2012)
Understanding the Classification System:
Using Classification to your Advantage™

Contains Nonbinding Recommendations

Guidance for Industry and Food and Drug Administration Staff

FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act

Document issued on: April 6, 2012

The draft of this document was issued on April 29, 2010.

OMB Control No. 0910-0705
Expiration Date: 3/31/2015

See additional PRA statement in Section VIII of this guidance

For questions for the Center for Devices and Radiological Health regarding this document contact the Premarket Notification (510(k)) Section at 301-796-5640.

For questions for the Center for Biologics Evaluation and Research regarding this document contact the Office of Communication, Outreach and Development at 1-800-835-4709 or 301-827-1800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

greenlight guru
71
Vascular Sciences
© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

Classification is NEVER Constant!

"It is not the strongest of the species that survives, nor the most intelligent that survives. It is the one that is most adaptable to change".

Charles Darwin

The only constant is change!

Understanding the Classification System:
Using Classification to your Advantage™
greenlight guru
76
Vascular Sciences
© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.


GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mldrues@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
36 Copyright 2020, Michael Drues, Ph.D.

How does classification vary around the globe?





Don't compare numbers!

i.e., Class II_{US} not necessarily = Class II_{EU} not necessarily = Class II_{ELSEWHERE}

Systems are fundamentally and philosophically different!

Understanding the Classification System:
Using Classification to your Advantage™

 83 **Vascular Sciences** 

© Copyright 2020 by Michael Druess, Ph.D.
and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)
www.greenlight.guru/webinar/medical-device-classification-system

Understanding the Medical Device Classification System: From Basics to Beyond – Using Classification to your Competitive Advantage™

Does a European database for medical devices exist?

Short answer:
Yes but...

European Databank on Medical Devices – EUDAMED
(May, 2014) available [here](http://ec.europa.eu/eudamed).



European Databank on Medical Devices - EUDAMED

The Medical Device Directives contain provisions on a European databank for medical devices, which has been developed under the name Eudamed. The aim of Eudamed is to strengthen market surveillance and transparency in the field of medical devices by providing Member State competent authorities with fast access to information on manufacturers and authorized representatives, on devices and certificates and on vigilance and clinical investigation data, as well as to contribute to a uniform application of the Directives, in particular in relation to registration requirements.

→ Which information is stored in Eudamed?

Depending on the applicable directive, Eudamed contains data on:

- registration of manufacturers, authorized representatives and devices,
- data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused,
- data obtained in accordance with the vigilance procedure and
- data on clinical investigations.

→ Who can access Eudamed?

Eudamed is a secure web-based portal acting as a central repository for information exchange between national competent authorities and the Commission and is not publicly accessible. Eudamed use is obligatory since May 2011.

The operational requirements and the security of the databank have been evaluated and the Eudamed Evaluation (381 KB) results are public.

EUDAMED database contains information on registration of manufacturers, authorized representatives and devices, data relating to certificates, data obtained in accordance with the vigilance procedure (so-called post-approval studies a.k.a. post-market surveillance) and data on clinical investigations. Access is restricted to the Medical Devices National Competent Authorities.

Understanding the Classification System:
Using Classification to your Advantage™
 85
Vascular Sciences
© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

MDDI, August, 2012

Classification	Risk Level	Device Examples
I	Low	Cervical collars, hospital beds, wheelchairs, stethoscopes, wound dressings.
IIa	Low-medium	Hearing aids, diagnostic ultrasound equipment, electrocardiographs, infusion pump tubing, dental bridges and crowns.
IIb	Medium-high	Tracheal cannulae, long term corrective contact lenses, peripheral vascular catheters, high-frequency electrosurgical generators, most therapeutic/surgical ultrasound equipment.
III	High	Cardiovascular catheters, neuro-endoscopes, absorbable sutures, left ventricular assisting devices (LVADs), drug eluting stents (coronary or pulmonary).

Classification in the EU

To sell device in EU, it must first be CE-marked:

- ✓ CE mark means device meets "essential requirements" (Annex I of Medical Device Directive)

CE Mark does not mean device is safe or effective!

- ✓ First step determine classification of device:
- ✓ MDD classifies devices into four categories based on 'risk'
- ✓ Characteristics that determine device classification include:
 - ✓ **Duration of patient contact**
 - ✓ Transient (<60min), continuous (>60min→<30days) or long term (>30days)
 - ✓ **Degree of invasiveness**, i.e., noninvasive, invasive via body orifice or surgically invasive
 - ✓ **Operative mode of action**, i.e., passive or active (source of power not gravity or human body)
 - ✓ **Effect on body**, i.e.,
 - ✓ local – limited to area where device is applied [Question: *Does any device really act locally?*] Or
 - ✓ systemic – effects of device may be outside area of application

Reality is much more complicated – regulatory logic is key!

Understanding the Classification System:
Using Classification to your Advantage™
 86
Vascular Sciences
© Copyright 2020 by Michael Drues, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldrues,
call (508) 887-9486 or e-mail mldrues@vascularsci.com

Taken from: *Designing Medical Products* Seminar Series
38
Copyright 2020, Michael Drues, Ph.D.

Understanding the Medical Device Classification System: From Basics to Beyond – Using Classification to your Competitive Advantage™

Classification in the EU

- ✓ Once device is classified in accordance with MDD, regulatory strategy can be planned
- ✓ General rule:
 - ✓ ↑ risk device → more rigorous regulatory process (i.e., ↑ *regulatory burden* – more hoops)
 - ✓ ↓ risk device → less rigorous regulatory process (i.e., ↓ *regulatory burden* – fewer hoops)
- ✓ But remember...



There are many connotations of risk

Risk_{USA} ≠ Risk_{EU}
- ✓ Some commonly used regulatory approaches for obtaining a CE mark shown →

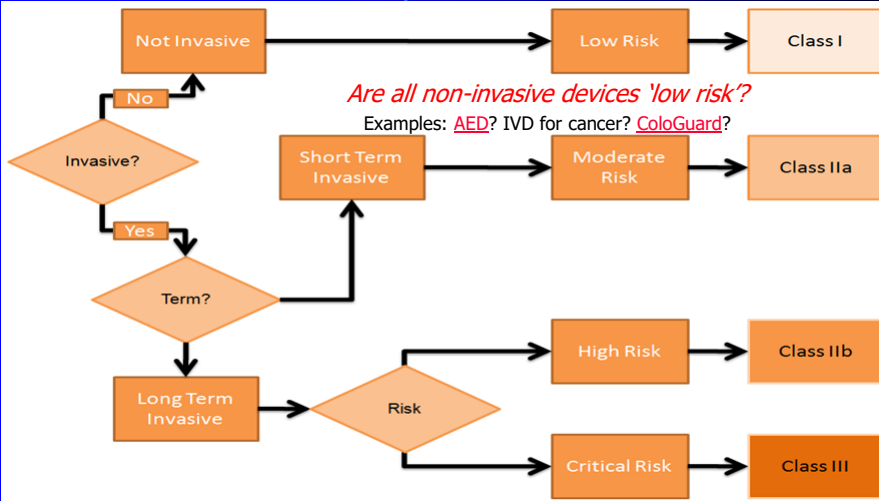
Global harmonization...
Why can't we all just get along?

Device Classification	Risk level	General regulatory process
I—nonsterile	Low	<ul style="list-style-type: none"> • Technical File (self-certification; does not require review by a Notified Body) + • EC Declaration of Conformity
I—sterile or measuring function	Low	<ul style="list-style-type: none"> • Technical File + • EC Declaration of Conformity + • Quality Management System compliant with ISO 13485 (or similar) + • Conformity assessment of Technical File & Quality System audit by Notified Body
IIa	Low-medium	
IIb	Medium-high	
III	High	<ul style="list-style-type: none"> • Design Dossier + • EC Declaration of Conformity + • Quality Management System compliant with ISO 13485 (or similar) + • Conformity assessment of Design Dossier & Quality System audit by Notified Body + • Notified Body exam/test/audit of product

An Engineer Takes on CE Marks and European Commercialization (MDDI, August, 2012)

Understanding the Classification System: Using Classification to your Advantage™  87  © Copyright 2020 by Michael Druess, Ph.D. and Vascular Sciences. All rights reserved.



EU Classification System



Are all non-invasive devices 'low risk'?
Examples: AED? IVD for cancer? ColoGuard?

Is it really so simple?

Absolutely not – this is why the 'regulatory logic' is most important!

Understanding the Classification System: Using Classification to your Advantage™  88  © Copyright 2020 by Michael Druess, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system


For additional information, www.linkedin.com/in/michaeldruess,
call (508) 887-9486 or e-mail mdruess@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
39 Copyright 2020, Michael Druess, Ph.D.

Understanding the Medical Device Classification System: From Basics to Beyond – Using Classification to your Competitive Advantage™


Is this what we really want?

How do I determine classification in the EU?



There's an App For That

What does *final classification estimate* mean?





CLASSIFY My Device
Brandwood Biomedical - Business

Everyone

This app is compatible with all of your devices.

Add to Wishlist

Install

BRANDWOOD-BIOMEDICAL-CLASSIFY

CLASSIFY is in accordance with Annex IX of the European Medical Device Directive.

Please enter the name of your device below:

catheter

OK

BRANDWOOD-BIOMEDICAL-CLASSIFY

Is catheter intended for?

TRANSIENT USE

SHORT TERM USE

LONG TERM USE, OR IS AN IMPLANTABLE DEVICE

BRANDWOOD-BIOMEDICAL-CLASSIFY

Further Classification Rule Information

Transient
Normally intended for continuous use less than 60 minutes.

Short term
Normally intended for continuous use not more than 30 days.

Long term
Normally intended for continuous use more than 30 days.

CLOSE

LONG TERM USE, OR IS AN IMPLANTABLE DEVICE

CLASSIFY My Device tells you the European classification of your medical device. The app uses simple step by step questions and answers to work through the Annex IX rules of the European Medical Device Directives and provide a final classification estimate for your device. You can go back and revisit any question at any stage.

Understanding the Classification System™ available [here](#).
Using Classification to your Advantage™

greenlight guru 89

Vascular Sciences

© Copyright 2020 by Michael Druess, Ph.D. and Vascular Sciences. All rights reserved.

EU Classification Guidance

EUROPEAN COMMISSION
DG HEALTH AND CONSUMER
Directorate B, Unit B2 "Cosmetics and medical devices"

MEDICAL DEVICES: Guidance document

Classification of medical devices

MEDDEV 2.4/1 Rev. 9
June 2010

GUIDELINES RELATING TO THE APPLICATION OF
THE COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES

Foreword

The present MEDDEV is part of a set of guidelines relating to questions of application of EU Directives on medical devices. They are not legally binding. Only the European Court of Justice can give an authoritative interpretation of Community Law.

This MEDDEV contains guidance for the application of the classification rules for medical devices as set out in Annex IX of Directive 93/42/EEC¹, as amended. It is for the national Competent Authorities and national Courts to take legally binding decisions on a case-by-case basis.

Directive 93/42/EEC, as amended, allows for derogation from the classification rules outlined in its Annex IX in light of technical progress or on information gathered from post-market experience with the device.

¹ OJ L 169, 12.7.1993, p. 1

Bottom line:

Classification of Medical Devices (EC, June, 2010) available [here](#).

Classification_{US} ≠ Classification_{EU} = or ≠ Classification_{other places}

Remember,

Think of classification (like risk) as a continuum!

Understanding the Classification System™ available [here](#).
Using Classification to your Advantage™

greenlight guru 91

Vascular Sciences

© Copyright 2020 by Michael Druess, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldruess,
call (508) 887-9486 or e-mail mdruess@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
40
Copyright 2020, Michael Druess, Ph.D.


Understanding the Medical Device Classification System: From Basics to Beyond – Using Classification to your Competitive Advantage™

Is this a 'regulated' medical device?

Short answer: ***It depends!*** On what? What it does? How it works?

Nope! What you say! a.k.a. "intended use"

What class? ***It depends!***



Case Study: *Migraine Headaches*

- ✓ Cefaly mobile non-invasive nerve stimulator delivers electrical energy via plastic band worn across forehead. Device stimulates trigeminal nerve believed to be associated with migraines. Patients >18 may use device for up to 20 minutes per day.
- ✓ [November, 2012] device class III because "it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II"

What is the 'default' classification of a 'new' device?

- ✓ [March, 2014] Manufacturer requested reclassification via de novo based on clinical trial (67 patients plus surveys of >2300 respondents)

Why clinical data? [risk mitigation? ...not so much. FDA vs. CMS]

- ✓ Approval set stage for other companies (510k) by citing Cefaly as substantially equivalent predicate device

Think competitive regulatory strategy!

(MassDevice, July 7, 2014) [here](#) / Federal Register (July 3, 2014) [here](#)

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru 99 **Vascular Sciences**


© Copyright 2020 by Michael Druess, Ph.D. and Vascular Sciences. All rights reserved.

Is this a 'regulated' medical device?

Short answer: ***It depends!*** On what? What it does?

Nope! What you say! a.k.a. "intended use"

What class? ***It depends!***



Case Study: *Migraine Headaches*

- ✓ "Special" (better 'specific') controls based on "potential risks" of technology include electrical/thermal hazards, ineffective treatment, misuse and adverse reactions

MassDevice, July 7, 2014

Identified risks	Mitigation measures
Failure to skin-contacting materials.	Biocompatibility testing. Labeling.
Electrical, mechanical, or thermal hazards that may result in user discomfort or injury.	Electromagnetic compatibility testing. Electrical, mechanical, and thermal safety testing.
Ineffective treatment.	Technical performance testing. Clinical performance data. Labeling.
Failure to identify the correct population.	Clinical performance data. Labeling.
Misuse that may result in user discomfort, injury, or delay treatment for headaches.	Labeling.

Remember...

There are many connotations of risk!

Federal Register (July 3, 2014)

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru 100 **Vascular Sciences**

© Copyright 2020 by Michael Druess, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldruess, call (508) 887-9486 or e-mail mdruess@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
41
Copyright 2020, Michael Druess, Ph.D.

Understanding the Medical Device Classification System: From Basics to Beyond – Using Classification to your Competitive Advantage™

Regulatory Strategy and Due-Diligence

510(k) Premarket Notification
FDA Home Medical Devices Databases

1 to 3 of 3 Results
Device Name: Cefaly Decision Date To: 07/09/2019 Results per Page: 10

New Search Export to Excel Download Files More About 510(k)

Device Name	Applicant	510(k) Number	Decision Date
Cefaly Dual	CEFALY Technology	K173006	11/28/2017
Cefaly Acute	CEFALY Technology	K171446	09/15/2017
Cefaly	CEFALY TECHNOLOGY	K160237	03/04/2016

July, 2019 [here](#).

Device Classification under Section 513(f)(2)(de novo)

FDA Home Medical Devices Databases

510(k) | De novo | Registration & Listing | Adverse Events | Results | PMR | IDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembly | Medical Reports | CLIA | TPLC

New Search Back To Search Results

Device Classification Name	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine
De Novo Number	DEN120019
510(k) Number	K122566
Device Name	CEFALY
Requester	STX-MED SPRL ZI Des Havens Sarts 4a Avenue 5 Hersel, Liege, BE 4040 Jean-Yves Migrolet
Contact	
Regulation Number	882.5891
Classification Product Code	PCC
Date Received	12/13/2012
Decision Date	03/11/2014
Decision	Granted (DENG)
Classification Advisory Committee	Neurology
Review Advisory Committee	Neurology
Reclassification Order	Reclassification Order
FDA Review	Decision Summary
Type	Post-NSE

July, 2019 [here](#).

Step I:
De novo
↓
Steps II, III, IV, ...:
Series of 510k's
Why?

Understanding the Classification System:
Using Classification to your Advantage™

101

© Copyright 2020 by Michael Druess, Ph.D. and Vascular Sciences. All rights reserved.

There are many regulatory consultants out there...
but there are surprisingly few good ones!
So how do you become a good one?

**Learn when to follow and
more importantly...
when to lead!**

**A MAN WHO WANTS TO LEAD THE ORCHESTRA
MUST TURN HIS BACK ON THE CROWD.**

MAX LUCADO

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

102

Vascular Sciences

© Copyright 2020 by Michael Druess, Ph.D. and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

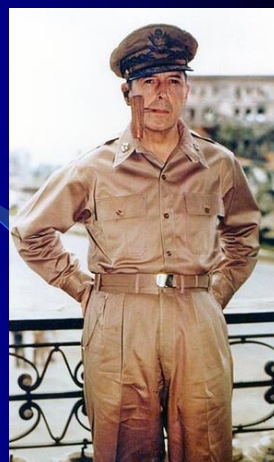
www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldruess,
call (508) 887-9486 or e-mail mdruess@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
42 Copyright 2020, Michael Druess, Ph.D.

Understanding the Medical Device Classification System: *From Basics to Beyond – Using Classification to your Competitive Advantage™*

Don't just follow the
rules... think!



***Rules are mostly made to be broken
and are too often for the lazy to hide behind.***

General Douglas MacArthur (1880 –1964) was an American general in the US Army during the 1930s and played a prominent role in the Pacific theater during World War II. He was one of only five men ever to rise to the rank of General of the Army in the U.S.

Understanding the Classification System:
Using Classification to your Advantage™

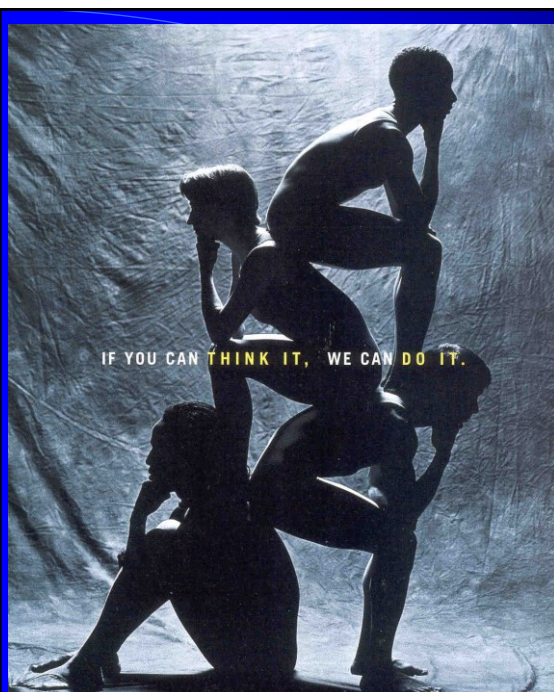
greenlight guru

103

Vascular Sciences

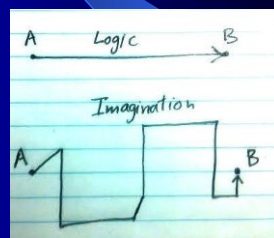


© Copyright 2020 by Michael Druess, Ph.D.
and Vascular Sciences. All rights reserved.



"Imagination is more
important than
knowledge, for while
knowledge points to all
there is, imagination
points to all that can be."

Albert Einstein



"Logic will get you from
A to B. Imagination will
take you anywhere."

Albert Einstein

Understanding the Classification System:
Using Classification to your Advantage™

greenlight guru

104

Vascular Sciences



© Copyright 2020 by Michael Druess, Ph.D.
and Vascular Sciences. All rights reserved.

GreenLight.Guru Webinar (July 16, 2020)

www.greenlight.guru/webinar/medical-device-classification-system

For additional information, www.linkedin.com/in/michaeldruess,
call (508) 887-9486 or e-mail mdruess@vascularsci.com

Taken from: *Designing Medical Products Seminar Series*
43
Copyright 2020, Michael Druess, Ph.D.