Understanding the Medical Device Classification System:

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

Presented by:

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and

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GreenLight.Guru Webinar (July 16, 2020)

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

For questions or more information, call
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Understanding the Medical Device Classification System:

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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 is 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 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.

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 & completive 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.

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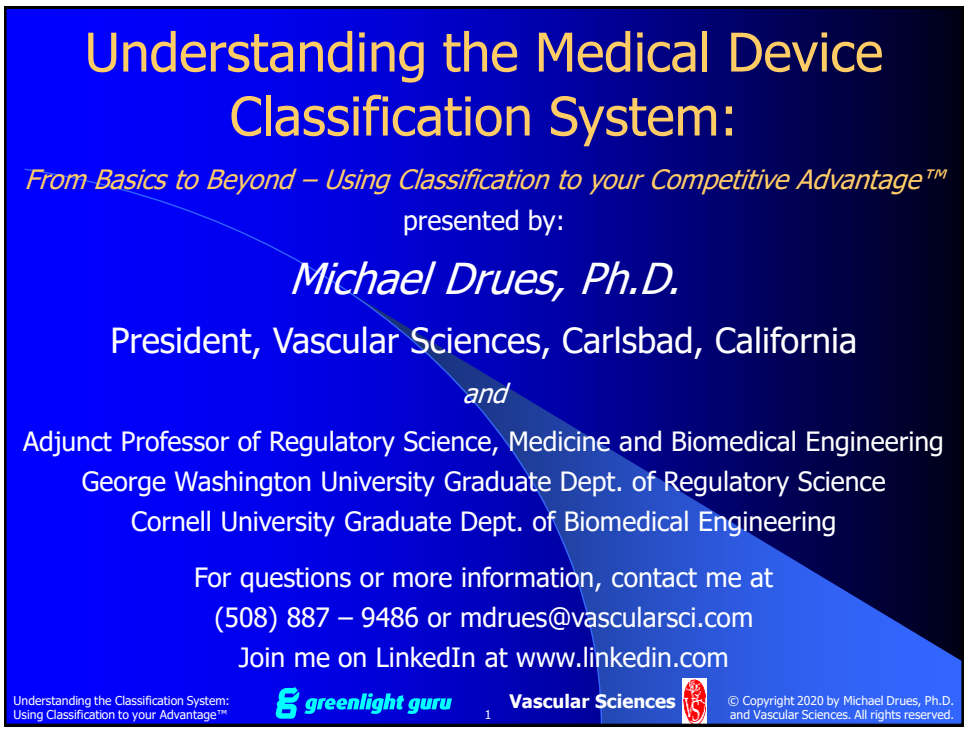

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First, an important disclaimer...

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!

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?

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Do you want more?

Classification: Basics and Beyond


MED DEVICE ONLINE

Design & Development | Regulatory | Manufacturing

Guest Column | July 2, 2014

Take Control Of Your Medical Device's FDA Classification

By Michael Drues, Ph.D., President, Vascular Sciences

If you're developing a medical device that's "substantially equivalent" to an existing device (i.e., a device currently on the U.S. market with similar labeling), then the FDA classification process can seem straight forward. Simply head over to the classification database on the CDRH website, enter the relevant information about your product, hit the search button, and viola! You can quickly determine whether your device fits into the Class I, II, or III category. At least, that's what most people think. Reality, however, is far more complicated, and there are exceptions to every rule. The best regulatory professionals know how to use the exceptions – not just the rules.

REGULATORY & COMPLIANCE

Guerilla Regulatory Strategy Tips And Tactics

A guest expert series by Michael Drues, Ph.D., President, Vascular Sciences

Recently I was asked by a venture capitalist to evaluate some new medical device technologies at an investor conference. One of the young entrepreneurs told me his new medical device was Class II. When


MED Device Online

Design & Development | Regulatory | Manufacturing | Logistics

Podcast | July 8, 2014

Who's In Control Of Your Medical Device's FDA Classification?

Medical device classification should be a pretty simple exercise, but as with most regulatory matters, it's not always as straightforward as it seems. In an effort to shed some light on the FDA's classification and reclassification process, Med Device Online's Jim Pronager connected with Dr. Michael Drues during the MD&M East 2014 conference in New York City. Mike is president of education and consulting company Vascular Sciences and a regular contributor on regulatory matters to Med Device Online. In this podcast, he discusses the typical routes medical device manufacturers take to device classification, how they can influence their device's classification, and why that can be to their competitive advantage.

If you are interested in learning more about device classification and reclassification, check out Dr. Drues' 90-minute online course on the subject, **Understanding the Medical Device Classification System: Best Practices for Selecting the Best Fit, which will take place on July 15, 2014, at 1 pm EDT time. For more information or to register, visit here.

Music credit: Morning Blue (Instrumental) (Josh Woodward) / CC BY 3.0

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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!

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Why is classification important

There are many reasons!

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 <u>most</u> travelled… unless it's to your advantage!

Short answer:

There are many of them…

and there are advantages and disadvantages of each!

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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)

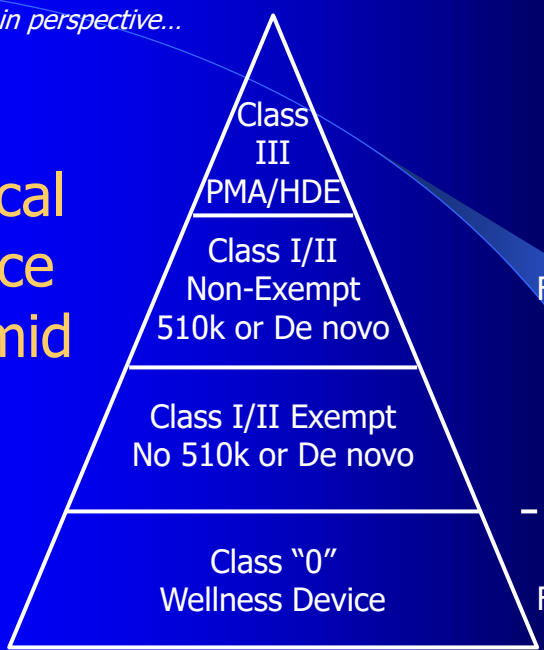
…and you can even mix and match!
Combination products?
Combination Regulatory Strategy

Plus:

Breakthrough Devices Program (BDP) and Safer Technologies Program (STeP)
BDP and STeP are not pathways *per se* but certainly worth considering

Putting things in perspective…

Medical Device Pyramid



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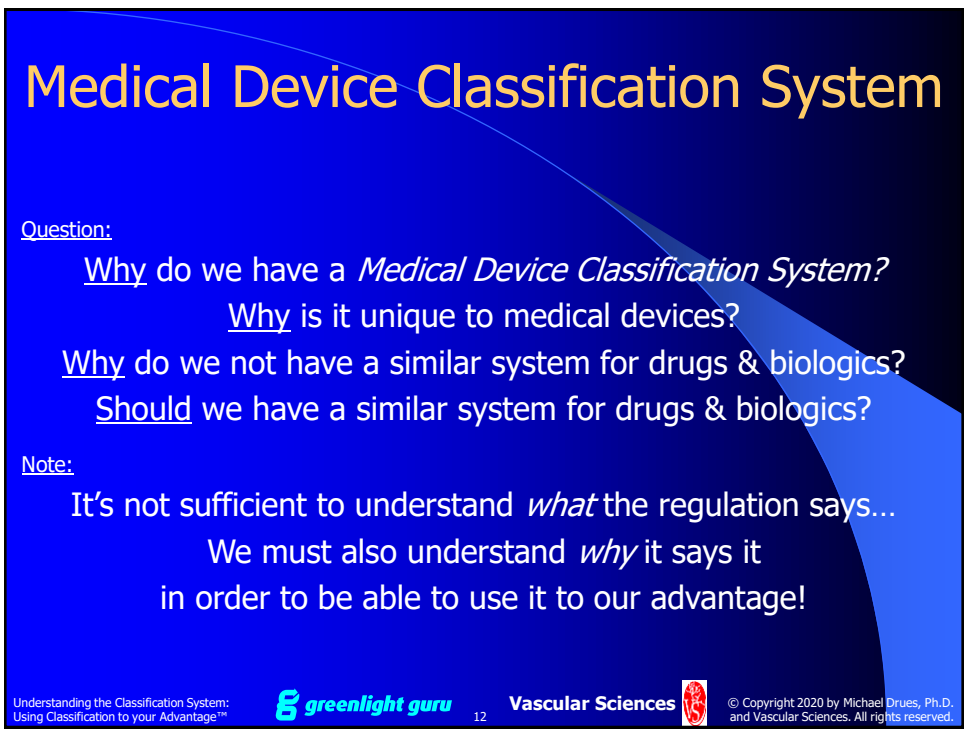

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Why do we have a medical device classification system?

Medical devices are not all created equal

Source: US FDA CDRH 2005 Strategic Plan

Medical Device Classification System ⇒ Stratification of Risk

This is the theory… in reality, there are <u>many</u> exceptions!

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?

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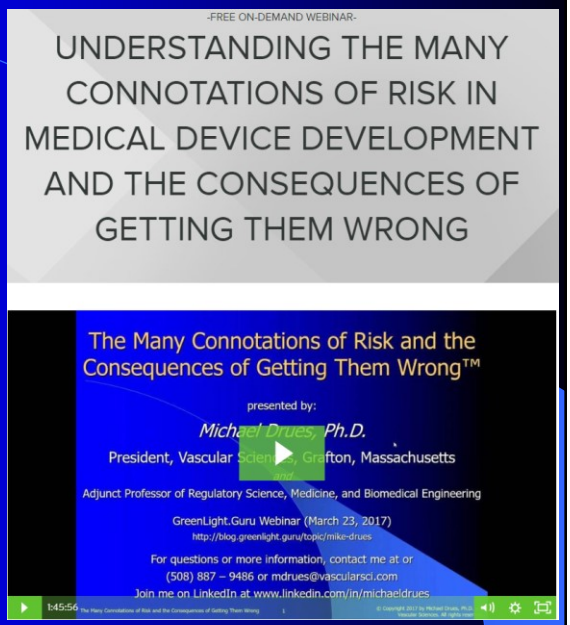
Want more?



www.greenlight.guru/webinar/many-connotations-risk-medical-device-development

Software Classification

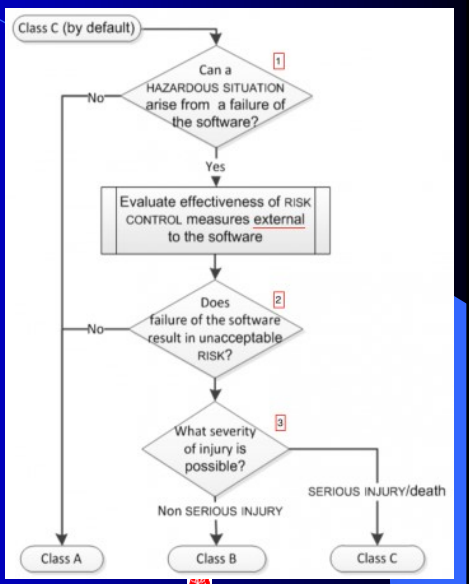
Is my software in class A, B or C?

- 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



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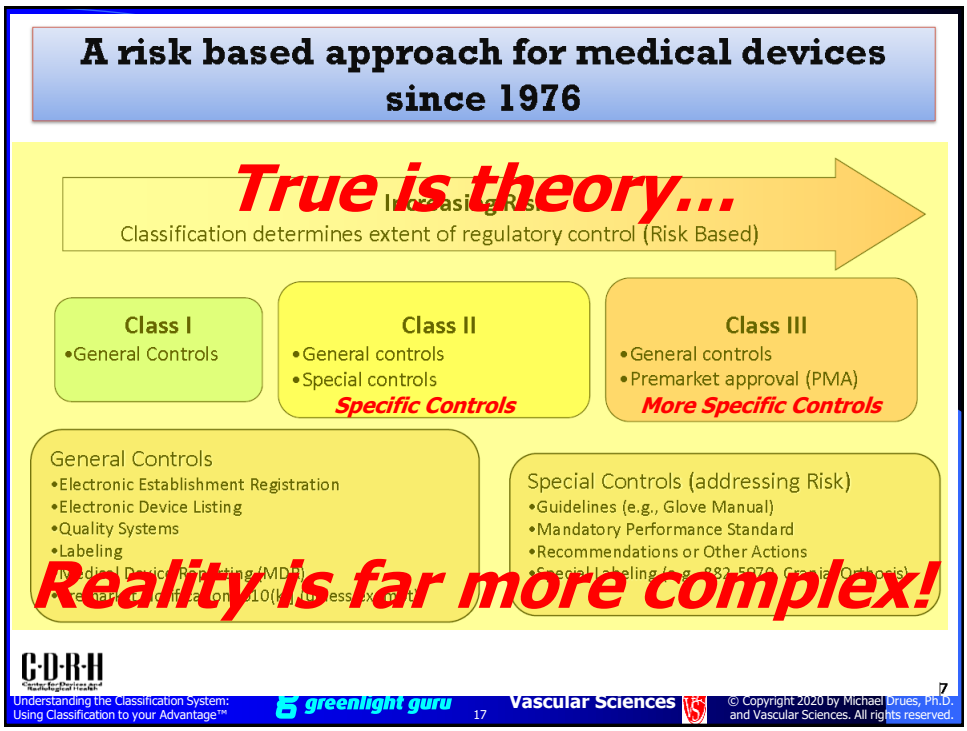

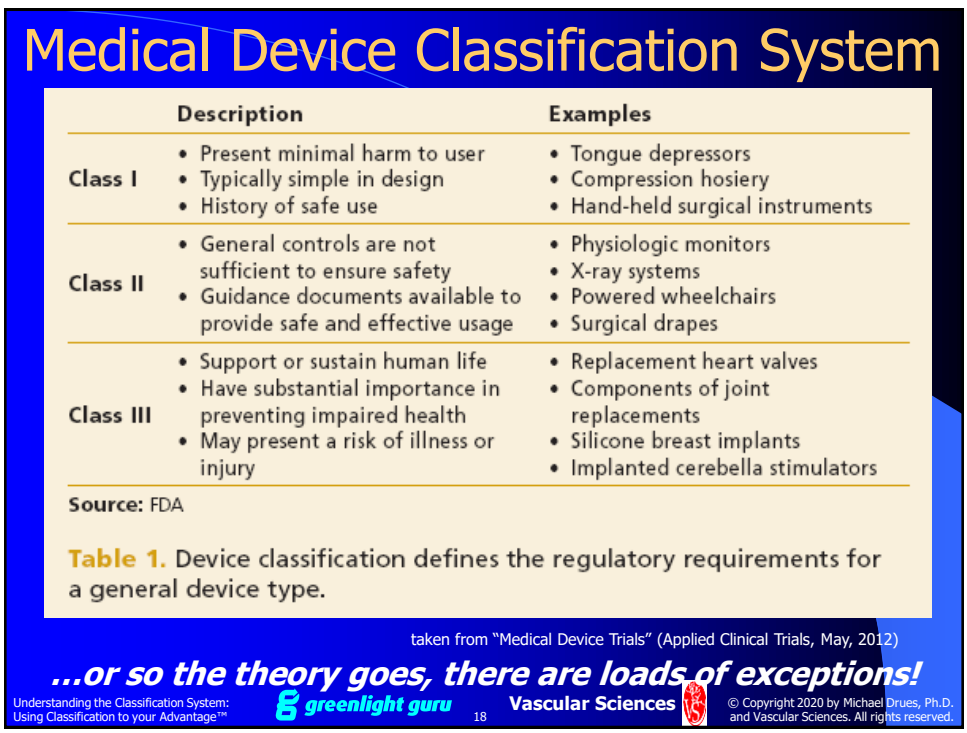

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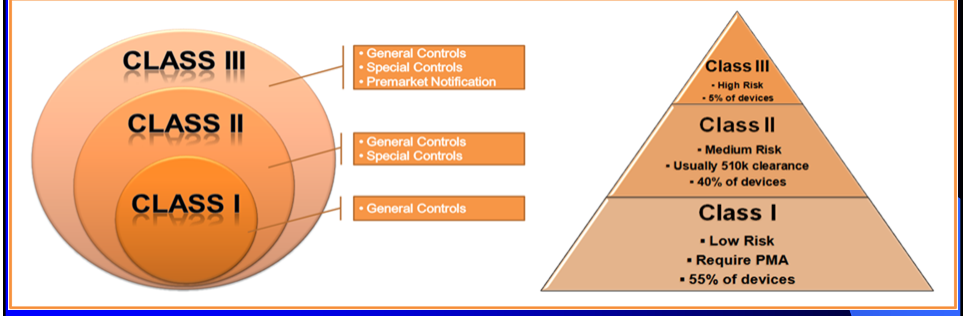
There are misttake(s) on this slide… can you find them?



Center for Emerging Neurotechnologies, University of Cincinnati

Is a hospital bed a medical device?

And if so, what class is it?

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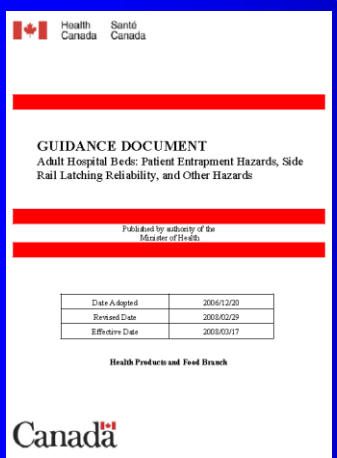
Is a hospital bed a medical device?

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

Today's Medical Developments, November/December, 2009

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 Ministries of Health

Date Adopted	2006/12/20
Revised Date	2008/02/29
Effective Date	2008/03/17

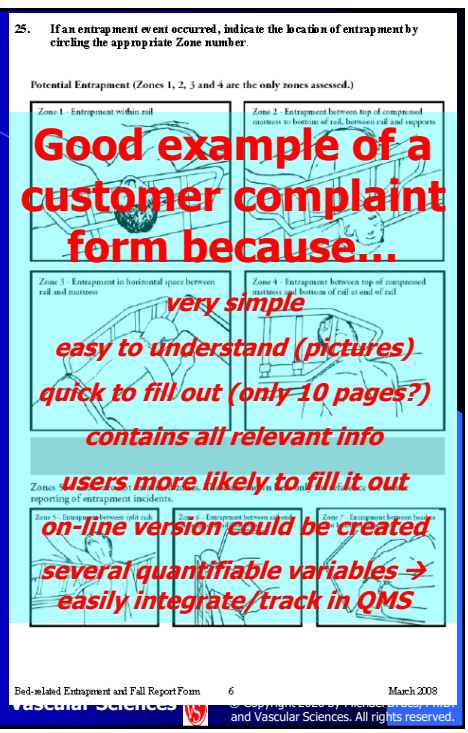
Health Products and Food Branch

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.


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

Zones 5, 6 and 7 are not assessed for the purpose of reporting of entrapment incidents.

Zone 5 - Entrapment between rail and mattress

Zone 6 - Entrapment between rail and mattress

Zone 7 - Entrapment between bed and mattress

Bed-related Entrapment and Fall Report Form 6 March 2008

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*

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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!

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?

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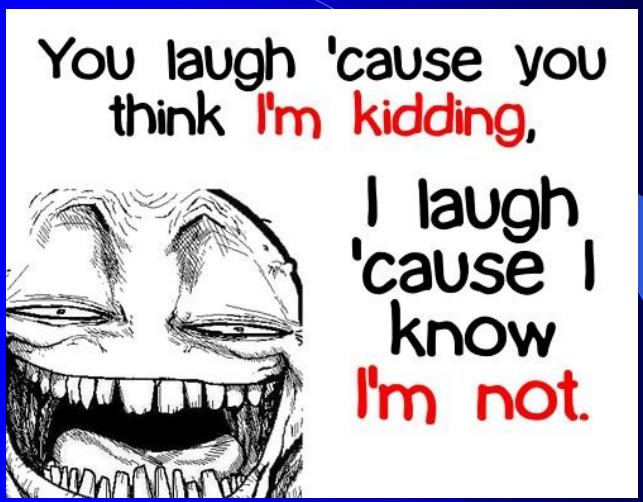
Think I'm joking?



Let's see why…

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?

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

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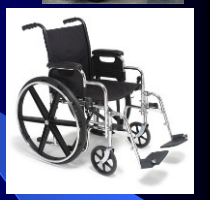
What is a medical device?

Is a 'go kart' a medical device?  How about an  ?

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

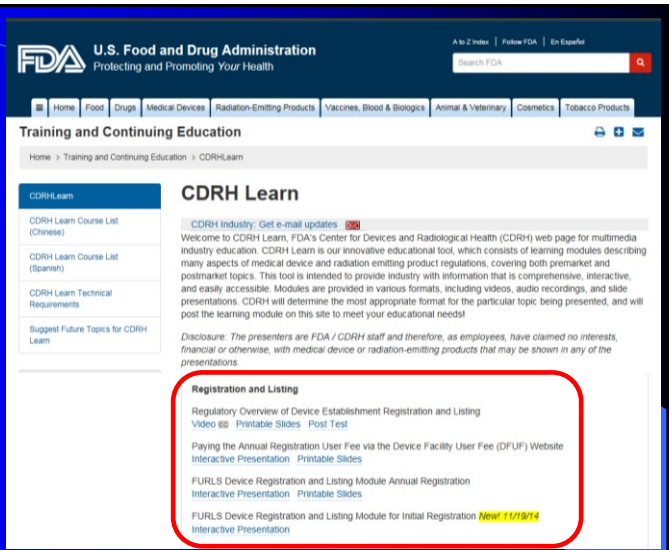
"A Tennessee maker of wheelchair components received an FDA warning letter after the agency determined some products advertised on the company's website had never been formally approved. The letter cited AireRx Healthcare with nine violations, including the company's online promotion of wheelchair cushions 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?

Back to registration…

Who needs to be FDA Registered and who does not?



www.fda.gov/Training/CDRHLearn/ [October, 2014]

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…

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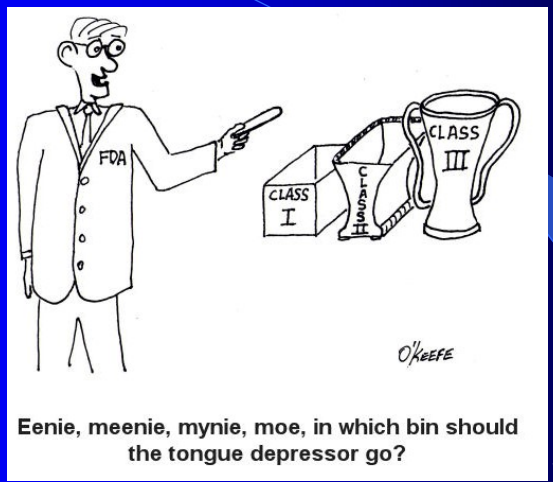
How do I determine the classification of my device

How do I determine the classification of my device?



Eenie, meenie, mynie, moe, in which bin should the tongue depressor go?

www.engineeringexpert.net

Bottom line:

Not nearly as simple as many think!

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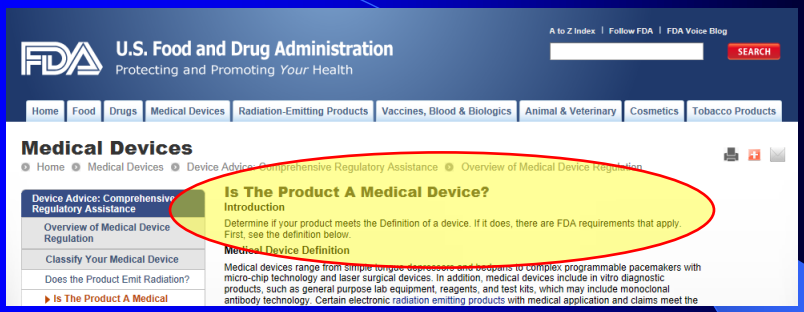
How do I determine the classification of my device?

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?

Is a ringtone a medical device?

The answer may not be as simple as you think!

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Thinking beyond phones and apps…

Is a ringtone a medical device?

Don't think so… not so fast!

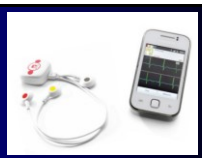
How about a ringtone that tells you you're having a heart attack? Not possible?

Think again!

So if a heart attack ringtone is a medical device… what class is it?

Hint: *what's the risk?*

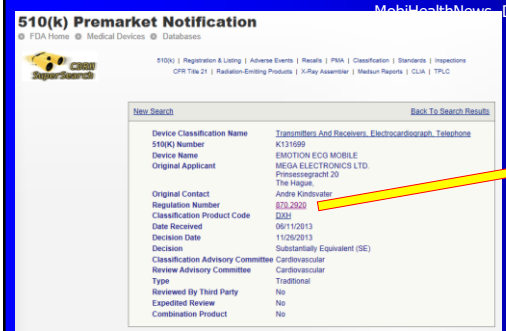
What class should this app be?



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

MobiHealthNews, Dec. 5, 2013



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

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

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!*

What if we raise the 'risk'

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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 arythmias

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)

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?

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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

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?

CDRH Website (April, 2014) [here]

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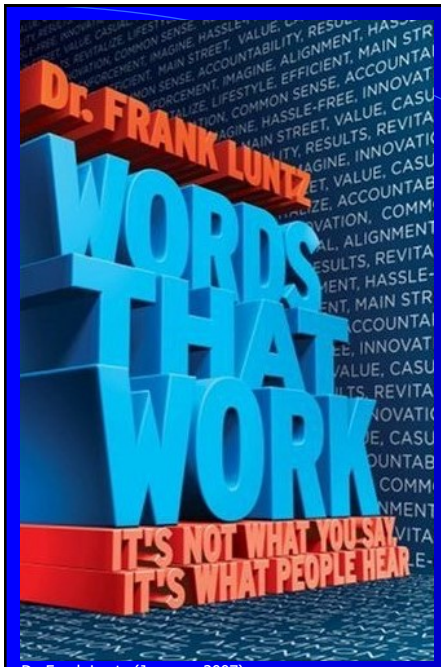

Dr. Frank Luntz (January, 2007)

Effective Communication

It's not what you say…

it's what people hear!

Zona Plus

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Understanding the Medical Device Classification System:

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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?

Case Study: Zona Plus

Note the claim:

Why is this important?

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Case Study: Zona Plus

Here is the answer:

ZONA HEALTH™ 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.

www.zona.com

What does this mean?

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:	890.5380
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…

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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 (DNPMD) 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

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 Register*s of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status [illegible] If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, 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

Why is this device Class I Exempt?

Product Code BXB available here

Case Study: Zona Plus

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

zona HEALTH™ The Power to Change™ | DEVICE | SCIENCE | REAL STORIES | 1-800-252-3810 | BUY NOW

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www.zona.com

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?

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

What is the classification of a video game?

Can a video game be a regulated medical device?

Case Study: EndeavorRx Video Game for ADHD

EndeavorRX Trailer (30 sec) here

EndeavorRx (DEN200026)
FDA Press release here
Product website here

"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.

EUA → De novo

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

What is the classification of a refrigerator?

Can a refrigerator be a regulated medical device?

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!

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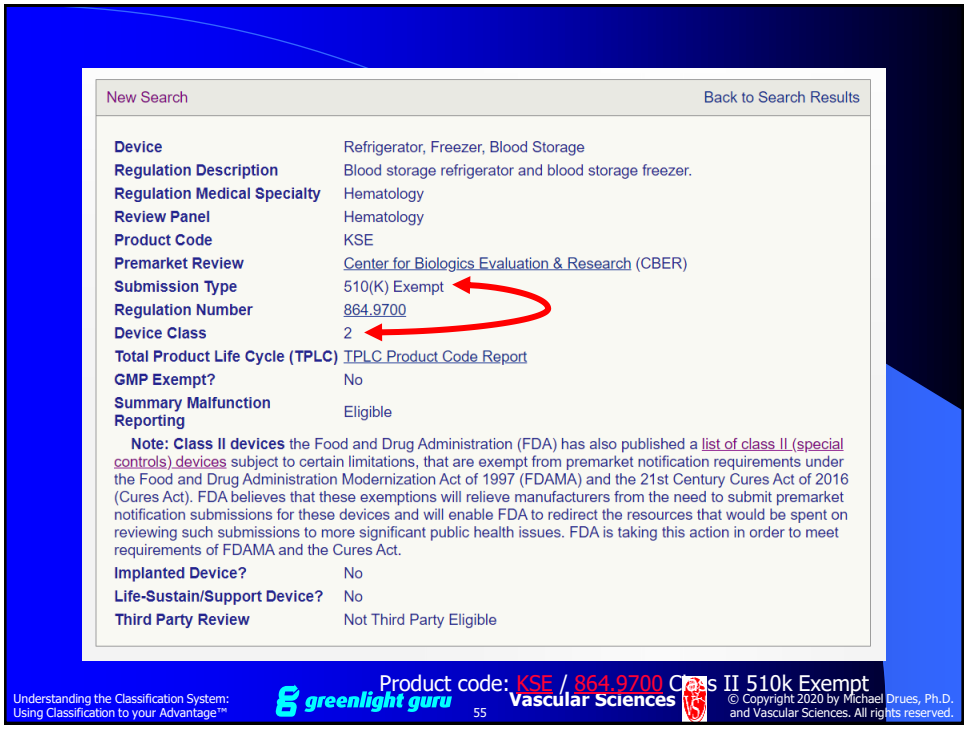

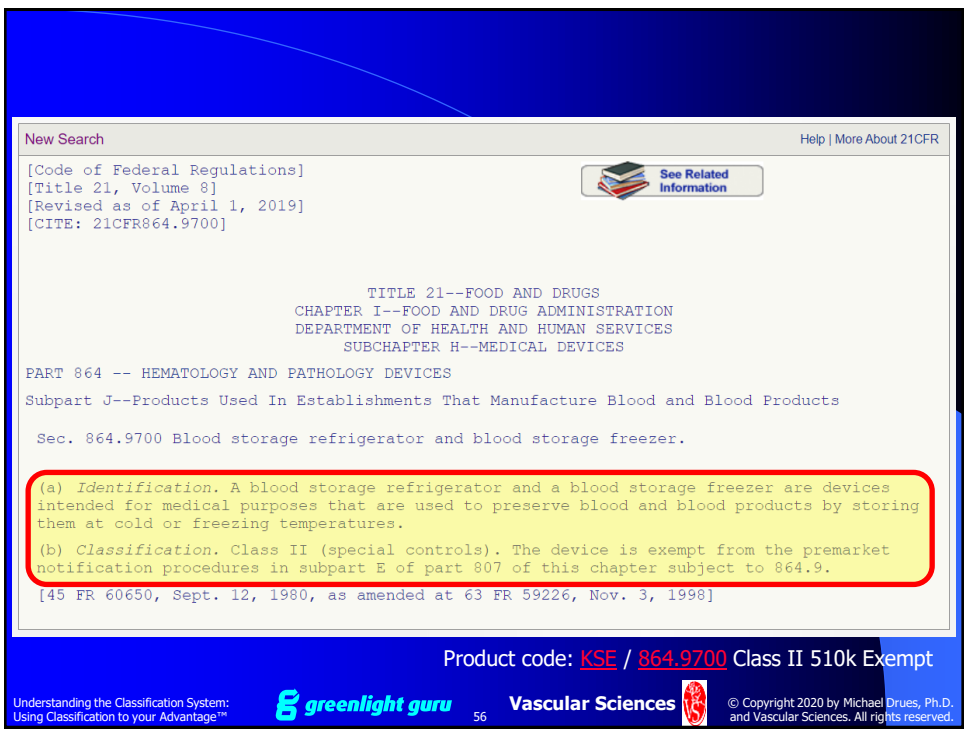

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Why class II?

Why 510k exempt?

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

What can happen when you get classification wrong

Sometimes it can be an expensive lesson learned!

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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.

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 15, 2020) here / Company website here)

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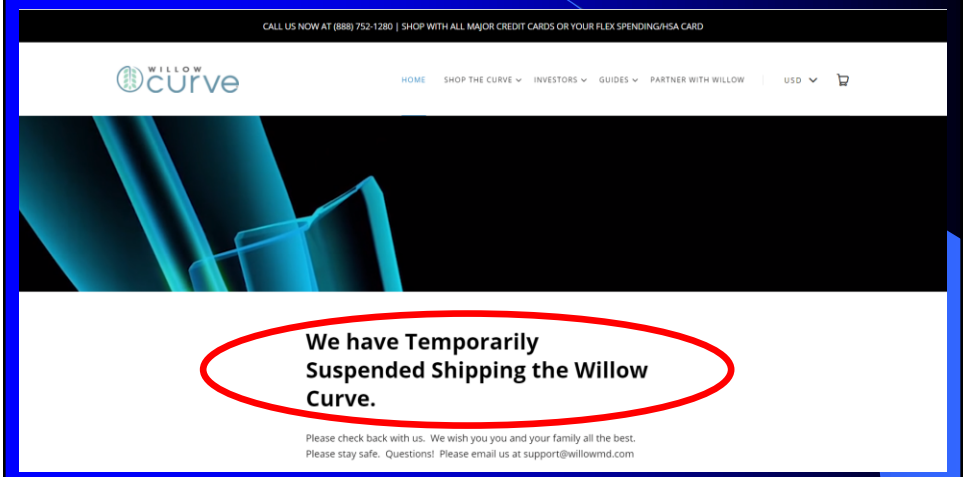
What can happen when you overplay your hand?



www.willowcurve.com (July 15, 2020)

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!

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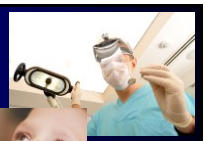
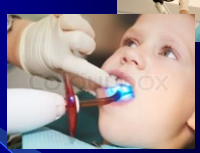
Regulatory Strategy Pyramid

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?

Another Classification Example





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

It depends!

On what?

Indication!

if $\text{indication}_{\text{Daylight}}$ [21CFR872.4620] OR if $\text{indication}_{\text{Bleaching}}$ [21CFR872.6475] → Class 1 Exempt
but if $\text{indication}_{\text{Curing}}$ [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	EXAMPLES
All other active devices are in Class I	- 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)

Does someone have to much time on their hands?

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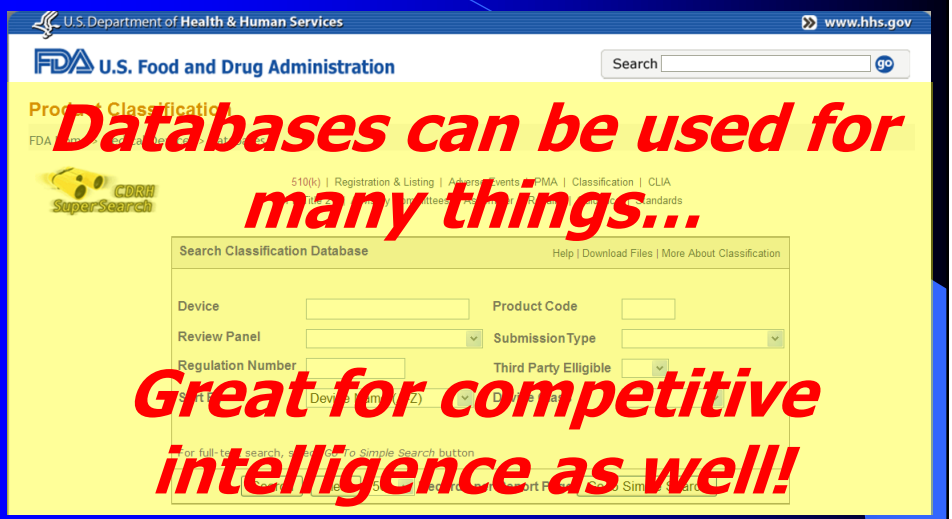
Device Classification Database



Databases can be used for many things…

Great for competitive intelligence as well!

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm

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!*

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What is and is not a 'regulated' medical device?

- ✓ Certain class I & II devices for which 510(k) review is not necessary to assure safety and effectiveness before these devices enter the market place ***because they are sufficiently well understood and do not present risks that require premarket notification (510(k)) review***
- ✓ Categories of devices include: Anesthesiology, Cardiovascular, Dental, ENT, GI/Urology, General & Plastic Surgery, General Hospital and Personal Use, Neurological Devices, OB/GYN, Ophthalmic and Physical Medicine Devices
- ✓ Regulatory 'logic' analogous to OTC drugs
- ✓ Guidance 'finalized' July 1, 2015 here

Intent to Exempt Certain Class II and Class I Reserved Medical Devices from Premarket Notification Requirements (CDRH, July, 2015) available here

Intent to Exempt Certain Class II and Class I Reserved Medical Devices from Premarket Notification Requirements

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

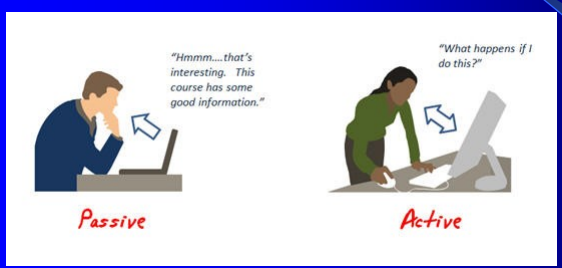
This guidance document is being distributed for comment purposes only.
Document issued on: August 1, 2014

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Abiy Desta at 301-796-0293 or by email at Abiy.Desta@fda.hhs.gov.

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

Must device classification be a "passive" process?



Short answer:

Absolutely not!

"Take Control Of Your Medical Device's FDA Classification" (Medical Device Online, July 2, 2014) available here.

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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. [illegible] basis for [illegible] with [illegible] classification [illegible];
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.

Isn't most of this obvious?

edited from CDRH website (July, 2014) available here

What if your device has not been classified

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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!

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

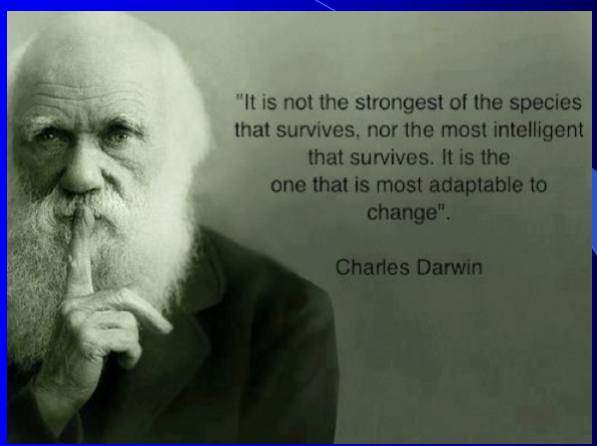
For questions for the Center for Devices and Radiological Health regarding this document contact the Premarket Notification (510(k)) Section at 301-796-5640.

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

Procedures for Section 513(g) Requests for Information (FDA, April, 2012)

Classification is NEVER Constant!



The only constant is change!

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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!

Time, cost and complexity of approval around the world

Please... ***take these numbers with a grain of salt!***

Emergo Group (Nov, 2015) available [here]

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Does a European database for medical devices exist?

Short answer:

Yes but...

European Databank on Medical Devices – EUDAMED (May, 2014) available here.

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.

MDDI, August, 2012

Classification in the EU

Classification	Risk Level	Device Examples
1	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).

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!

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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

$Risk_{USA} \neq Risk_{EU}$

- ✓ Some commonly used regulatory approaches for obtaining a CE mark shown →

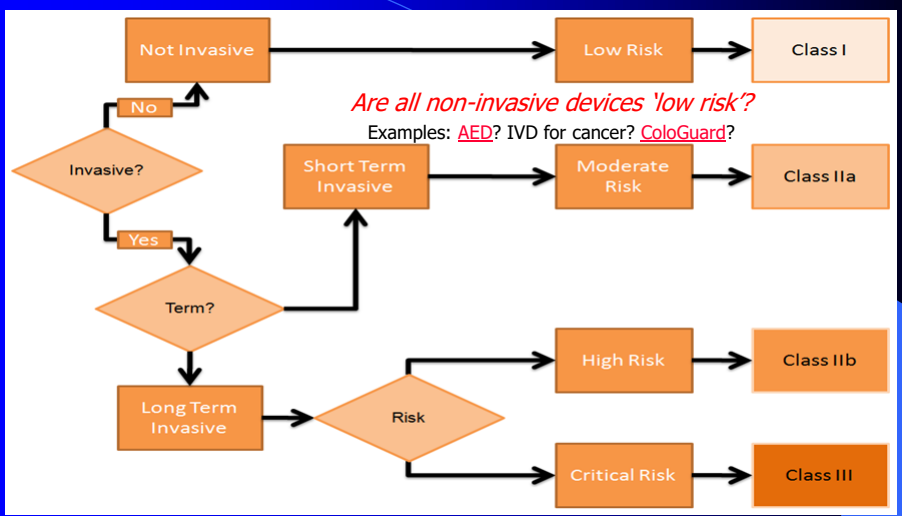
Device Classification	Risk level	General regulatory process
I—nonsterile	Low	• Technical File (self-certification; does not require review by a Notified Body) + • EC Declaration of Conformity
I—sterile or measuring function	Low	• Technical File + • EC Declaration of Conformity + • Quality Management 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	• 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

Global harmonization…

Why can't we all just get along?

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

EU Classification System



Is it really so simple?

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

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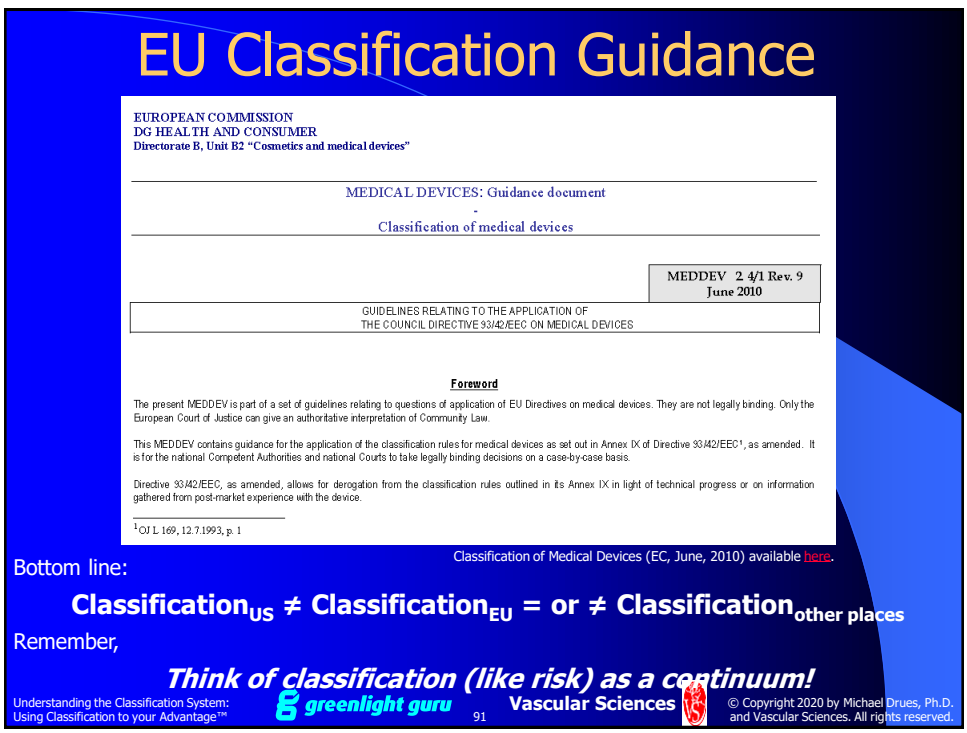

GreenLight.Guru Webinar (July 16, 2020)

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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

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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

Table 1--Transcutaneous Electrical Nerve Stimulator To Treat Headache Risks and Mitigation Measures

Identified risks	Mitigation measures
[illegible] 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. Technical parameters. [illegible] testing. Software validation, validation, and hazard analysis.
Ineffective treatment.	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.

Federal Register (July 3, 2014)

Remember…

There are many connotations of risk!

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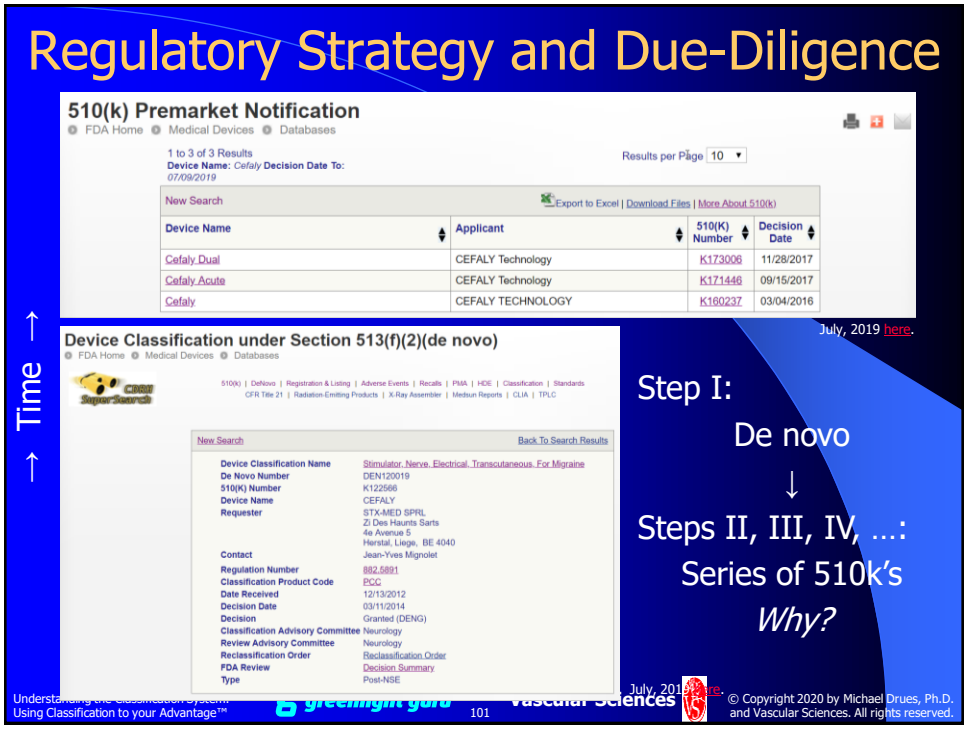

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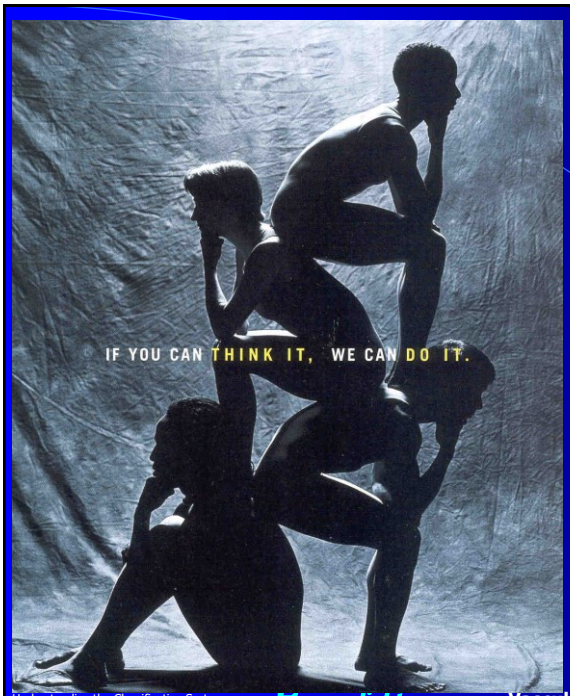
Don't just follow the rules… think!

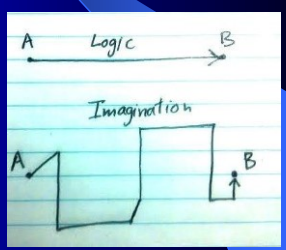
Rules are mostly made to be broken
and are too often for the lazy to hide behind.

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.



"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

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