Live Q&A with FDA

Cybersecurity Premarket Guidance

April 3, 2024

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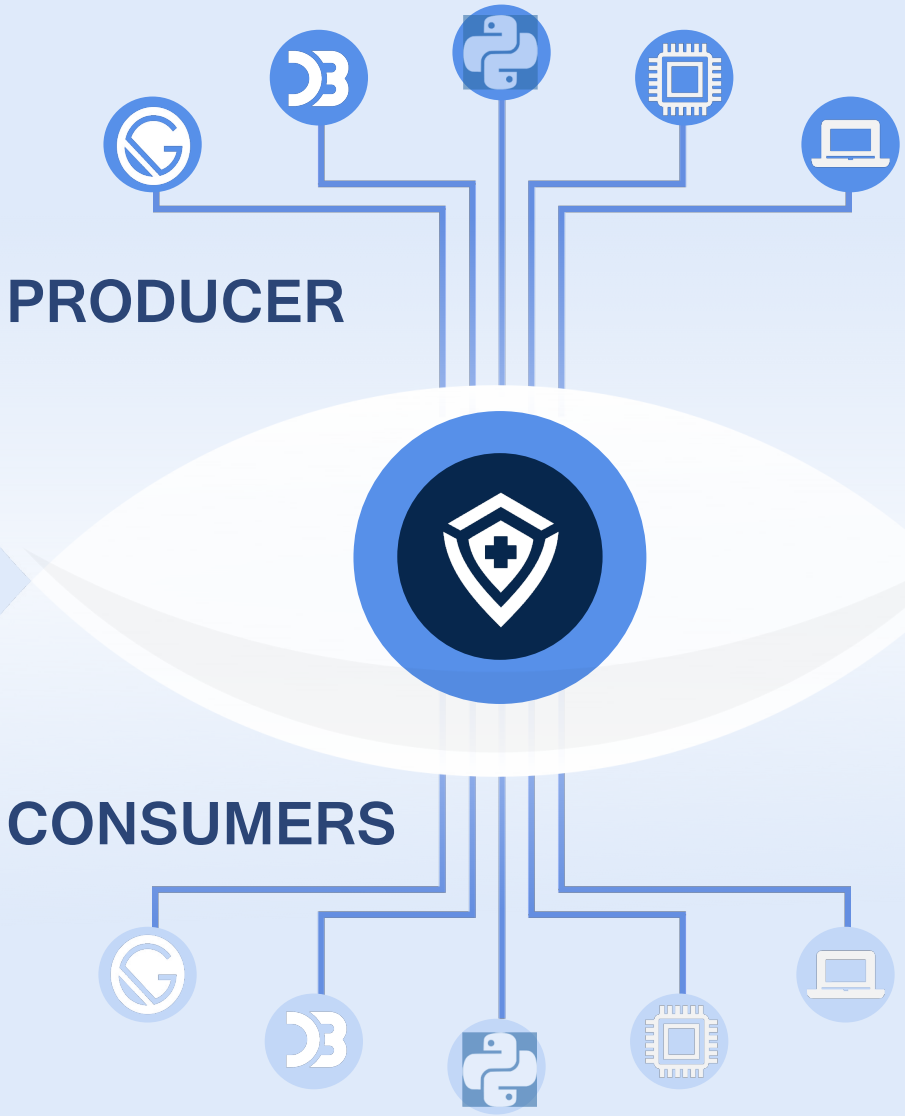

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Question #1

Are there specific requirements for AI-enabled devices?

Question #2

On CVE reports and statistics that can be supplied, what level of detail is needed for CVEs unpatched but mitigated on the device (e.g. by hardening and configuration)?

Question #3

Where does cybersecurity fit into the software lifecycle TPLC?

Question #4

Do these FDA requirements align with IEC 81001-5-1:2022 (Health software and health IT systems safety, effectiveness and security), which is now mandatory for medical devices in the EU?

Question #5

As this guidance is for 510(k)s moving forward, what is the guidance for devices that are currently in the marketplace (i.e. legacy medical devices)? Do they effectively get a pass?

Question #6

Are there FDA expectations on the timeframe from exploit discovery to patch completed in-the-field? Or are those time frames coming?

Question #7

Not much guidance is provided in the post-market guidance for CVD (it says refer to the recognized standard). Could you briefly go over what FDA will specifically look for?

Live Audience Questions

Now we'll take *your* questions!

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