FormlyAI

Shortest Path to Medical Device Approval

ABHI Kickoff Bootcamp
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CEO & Co-Founder

vs.

EU / UK Regulations

- Classification rules
- “Prove it” approach
- Decentralized regulatory bodies
- Stricter post-market surveillance

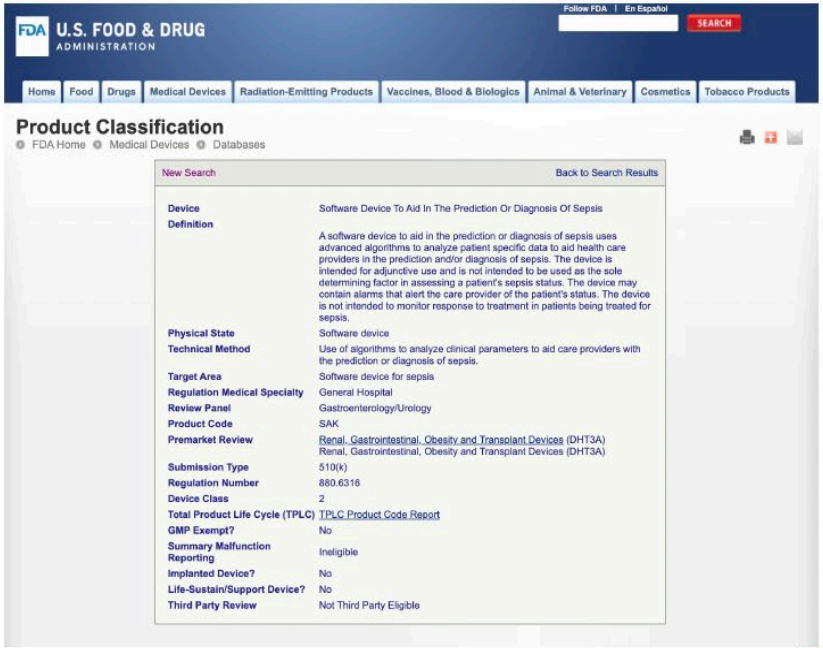
US Regulations

- Product codes
- Prescriptive approach
- Centralized regulatory body
- More flexible on low risk software

FDA Product Codes

Product code – 3 letter code assigned to devices regulated in a similar way

- Devices bucketed into “like” groups under product codes (drives classification)
- Product codes will define your regulatory path to market
- De Novo creates a new product code pathway for novel devices
- Each product code is handled by a different division who will review your submission



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Product Classification

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Device	Software Device To Aid In The Prediction Or Diagnosis Of Sepsis
Definition	A software device to aid in the prediction or diagnosis of sepsis uses advanced algorithms to analyze patient specific data to aid health care providers in the prediction and/or diagnosis of sepsis. The device is intended for adjunctive use and is not intended to be used as the sole determining factor in assessing a patient's sepsis status. The device may contain alarms that alert the care provider of the patient's status. The device is not intended to monitor response to treatment in patients being treated for sepsis.
Physical State	Software device
Technical Method	Use of algorithms to analyze clinical parameters to aid care providers with the prediction or diagnosis of sepsis.
Target Area	Software device for sepsis
Regulation Medical Specialty	General Hospital
Review Panel	Gastroenterology/Urology
Product Code	SAK
Premarket Review	Renal, Gastrointestinal, Obesity and Transplant Devices (DHT3A) Renal, Gastrointestinal, Obesity and Transplant Devices (DHT3A)
Submission Type	510(k)
Regulation Number	880.6316
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

Each submission is different

Why does everyone like 510(k)?

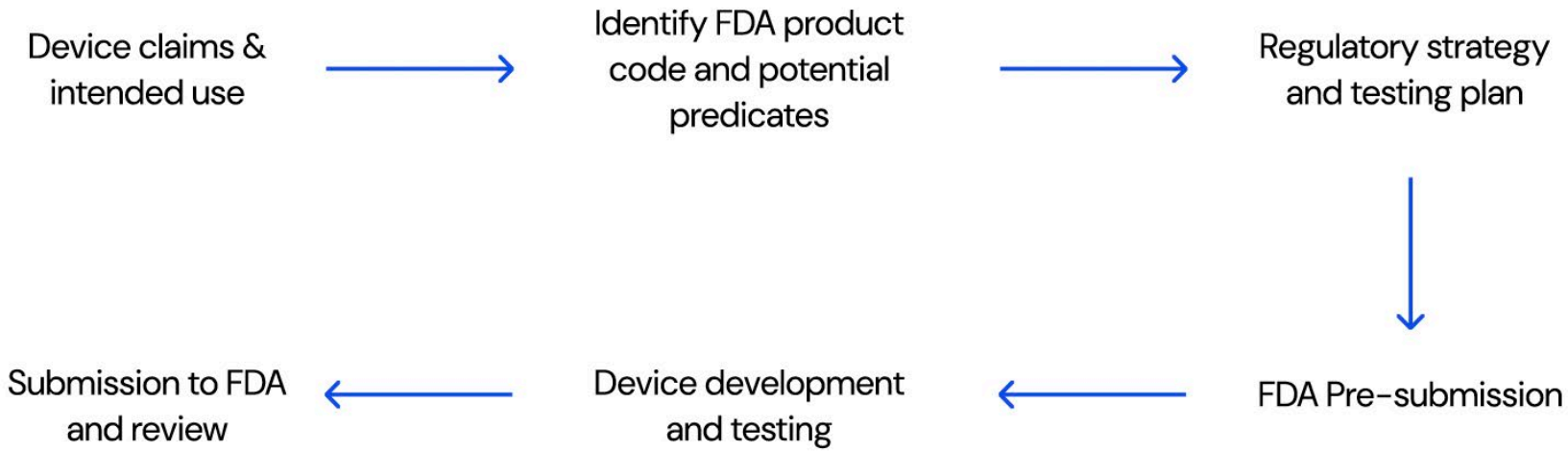
95% success rate

No clinical data often required

Clear testing requirements from predicate

90 day review cycle

What does prep for FDA submission look like?



There is often multiple paths to market

Path 1 – Fast to market, limited

- Develop device with limited claims
- Perform device testing without clinical study
- Get limited claims version on market through 510(k) pathway
- Sell MVP product while developing AI algorithm
- Do follow on 510(k) to get AI version of product approved
- Full feature set device on market

Path 2 – Slow to market, full features first

- Develop device with some novel features
- Perform prospective clinical study for validation
- Do a 510(k) submission with reference predicate to bridge technology gaps
- Full feature set device on market

Pre-Submissions de-risk your submission

Pre-submissions allow you to reach out to the FDA ahead of time and ask them questions about your device's regulatory and development strategy ahead of your submission.

Q-Submissions de-risk your submission

Reach out early	Review takes time (~75 days) so get your questions to FDA early. It's also free to submit!
Do your research	The more actionable information you can ask FDA the better feedback they can give. Ask about strategy, predicates, testing protocols, and more. Do NOT ask open ended questions.
Listen to FDA	This is your chance to meet the FDA and their chance to meet you, listen to their feedback. Often multiple pre-submissions are needed.

Details from pre-submission meetings can be reviewed during your future submission.

A note for AI companies on the PCCP

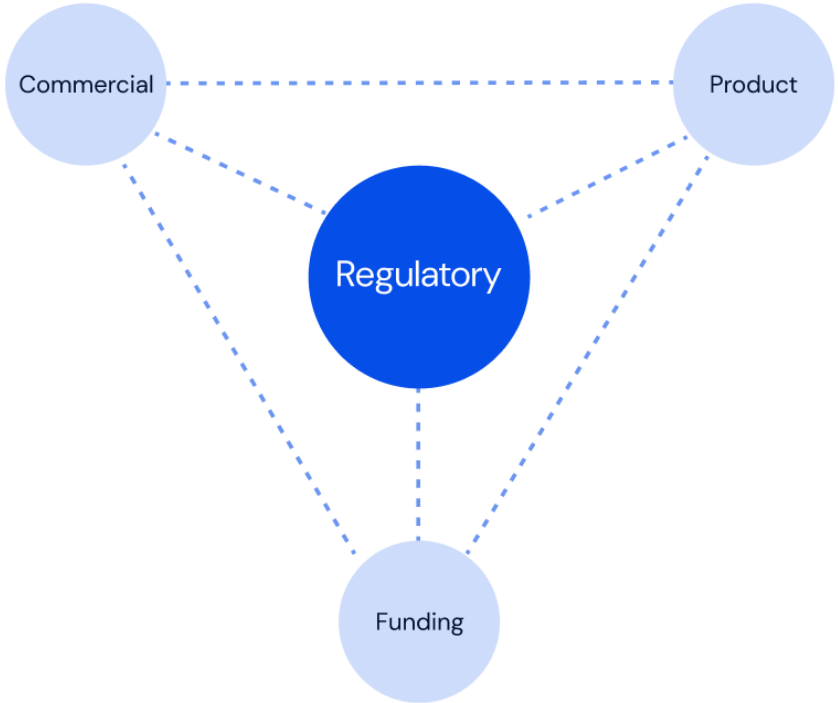
- Pre-determined change control plan (PCCP) - make pre-planned changes to your algorithm without needing a new submission
- It cannot alter or expand the intended use of the product
- FDA likes to see changes that are allows vs not allowed, acceptance criteria, and the changes impact on the existing product
- Include your PCCP in your pre-submission for FDA sign off!

Software Products at FDA

- More flexibility on claims than UK / EU with options for Clinical Decision Support, wellness, and MDDS as to be non-regulated products
- There are few Class I Software products.. most low risk software falls under Enforcement Discretion
- There are limited product codes for SaMD so sometimes 510(k) pathway is difficult
- For connected devices, the introduction of “cyber devices” significantly expands cybersecurity requirements

Check out FDA’s Digital Health Policy Navigator!

Regulatory strategy enables market access



Some key take aways

- Many paths to market – Start with knowing the product you can sell and work backwards to your regulatory strategy
- Your claims drive your device classification more than your technology
- Pre-submissions are critical early to avoid costly mistakes (but make sure you're asking the right questions!)
- FDA's treatment of Software and AI products is complicated and still evolving

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Breakthrough and STeP programs

Breakthrough program

- For devices treating life-threatening or irreversibly debilitating conditions with no approved alternative
- Mechanism to engage with FDA more during development process, doesn't speed your path to market as review windows stay the same

Safer Technologies Program (STeP)

- Voluntary program for devices offering a safer alternative to treatments already on the market