

MEDICAL DEVICE REGULATORY STRATEGY KEY PRELIMINARY QUESTIONS

While obtaining FDA marketing approval of your innovative medical device may seem like a far off milestone, it can be beneficial to consider regulatory implications for your idea in the early stages of development to optimize your device design and prepare for this future milestone. Here are some Key Medical Device Regulatory Strategy Questions to consider that can impact how your invention could be regulated by the FDA:

Have you reviewed the [FDA's Four Steps](#) to bring a device to market?

What are your invention's [intended use](#) and [indication for use](#)?

- Medical condition or disease to be treated
- Use – diagnosis, prevention, symptom relief, cure?
- Patient population – adults, pediatrics, all?

Based on your invention's intended use and indications for use, does your product meet the [definition of a medical device](#)? If yes, what is the appropriate classification?

What [level of risk](#) does your invention pose to the relevant patient population?

- Low – minor to no harm
- Moderate – minor, temporary or medically reversible Injuries
- High – death or life-threatening injury and illness, permanent impairment or damage that requires medical or surgical intervention

What is the [development stage](#) of the product?

- Concept, prototype, bench or animal testing? Usability?
- A planned clinical study may need to be submitted for approval under Investigational Device Exemption submission.

How [similar is your product](#) to any other products currently on the market?

- This can impact the type of marketing submission and regulatory requirements.
- If similar, is there an FDA website for the similar device that notes the device's product classification/regulation number and product code that could apply to your device?
- Note the "Other Databases" panel on the right of the web page as not all devices will be 510(k) eligible.

Have you checked out [CDRH Learn](#), [Device Advice](#), or researched if there are any FDA resources that relate to your invention?

- Searching for general terms with "FDA" can help find FDA related resources.

Have you interacted with the FDA yet or have an idea of how to start the process?

- [Division of Industry and Consumer Education \(DICE\)](#) for general questions
- [Q-submission Program](#) to request feedback from or a meeting with FDA/CDRH staff
- Note that a significant change in an approved medical device could require a new premarket submission regardless of the regulatory pathway.

NEED HELP? Contact us to discuss and be connected to further resources.

Check out our [Digital Library](#), which includes a Basic Resource Guide and a 510(k) Checklist.

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EXAMPLE: AUTOMATED EXTERNAL DEFIBRILLATORS (AEDS)

What is your invention's intended use?

- AEDs use external electrodes, hardware, firmware, and software to detect and interpret an electrocardiogram and deliver an electrical shock

What is your invention's indication for use?

- AEDs are indicated to be used by trained individuals to deliver energy for defibrillation, cardioversion, external pacing, and ECG monitoring applications
- AEDs can be used on adults and children.

Based on your invention's intended use and indications for use, does your product meet the definition of a medical device?

- Yes, AEDs are instruments that are intended to mitigate and treat applicable cardiac dysrhythmias. AEDs utilize software, but it is not solely a software program and requires hardware for use. They are not intended for general wellness and do not incorporate the use of drugs and biologics. They require accessories like batteries and electrode pads.

What level of risk does your invention pose/what classification may be relevant to your device?

- High – AEDs are used for live-saving measures.

What stage of development are you in?

- Hypothetical finished AED has been developed and tested in a usability and clinical study.
- Clinical study information can be leveraged from published studies and clinical data previously submitted to the FDA.

How similar is your product to any other products currently on the market?

- The hypothetical AED is similar to other devices on the market, which are regulated as Class III medical devices under product code MKJ, which require submissions of Pre-market Applications (PMA) to FDA.

Have you checked out CDRH Learn, Device Advice, or researched if there are any FDA resources that relate to your invention?

- Guidance Document: Necessary Automated External Defibrillator Accessories: Policy Regarding Compliance Date
- FDA Website on Automated External Defibrillators (AEDs)

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