This information should not be considered to represent advice or guidance on behalf of the U.S. Department of Health and Human Services or any agency or office thereof.

CDRH Small Business Support – The Division of Industry and Consumer Education (DICE)

Context

NIH small businesses often wonder how to approach FDA for the first time. For medical device innovators, the Division of Industry and Consumer Education (DICE) makes that simple!

Think of DICE as the friendly Customer Support/Information Desk for all of FDA's Center for Devices and Radiological Health to help get you started with the right resources! Not sure who to talk to about your software product? – DICE can direct you to reviewers or subject matter experts across the center. Not sure where to find guidance on biocompatibility? – DICE can help you locate relevant documents to your products development and regulatory pathways. Curious about compliance obligations during clinical studies or after your product is approved? – DICE can help break them down so you can understand the requirements.

DICE's mission includes educating and informing the medical device industry about FDA regulations, policies, and guidance.

This article will provide an overview of the services DICE offers:

- What resources has DICE made available online?
- What questions is DICE well-suited to answer?
- And what questions are better suited for a Q-submission with CDRH review staff?

DICE provides outstanding customer support, so do not hesitate to contact them as early and as often as you need. You can reach out to DICE staff by telephone or email.

Email: DICE@fda.hhs.gov

Phone: 1(800) 638-2041 or (301) 796-7100
Press 1 to speak to the Consumer Team
Press 2 to speak to the Industry Team

Online Resources

DICE provides and maintains two online resource catalogues to educate the medical device community: Device Advice and CDRH Learn.

Device Advice

Device Advice is a comprehensive text-based resource featuring over 300 pages of regulatory education materials organized by subject matter. These pages include many helpful articles with tables that organize regulatory information in a digestible format. There are many direct links to relevant databases, regulations, policies, or organizations throughout these documents. The overall structure is framed as "Bringing a Device to Market" with dozens of topics and subtopics. For example, to learn about Class I or Class II exemptions, navigate as follows:
Device Advice / Overview of Device Regulations / Classify Your Medical Device / Class I and Class II Exemptions.

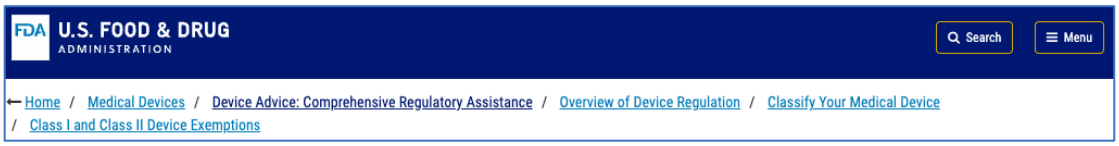

Figure 1. The top of the web page shows your current location within the Device Advice content framework.

Device Advice is a great place to browse and become familiar with how CDRH operates, what regulatory distinctions are for medical devices, and generally what to expect on your commercialization journey.

CDRH Learn

CDRH Learn is a multimedia library of over 200 educational modules, slides, videos, webinars, and instructional "how to guides" related to medical device and radiological health regulation. The list of topics is continually expanding, as FDA hosts new meetings and recordings are uploaded. In most cases, the transcript and slides from the presentations are available for download for future reference. The current categories of media include:

- The Basics
- How to Study and Market Your Device
- Postmarket Activities
- In Vitro Diagnostics
- Unique Device Identification System
- Specialty Technical topics
- Radiation-Emitting Products
- 510(k) Third Party Review Program
- Industry Basics Workshop Series

Each category contains multiple related subtopics and links to associated presentations.

Interacting with DICE

Nobody knows the educational materials for medical devices as well as DICE. That's why sending an email to DICE is the best place to start learning about specific FDA programs, guidance, or policy. If they cannot answer your inquiry, they will do their best to find someone that can.

Questions involving the regulatory requirements for an exact medical device may be too specific for DICE to address and are better suited for a Q-submission meeting with FDA review staff. This is especially true if the questions are contingent on understanding the nuances of the medical device that you are developing.

Good DICE requests	Good Q-sub requests
How do I qualify as a small business with CDRH?	Based on this detailed device description, does FDA agree that the device is exempt?
I need help understanding a specific chapter of a guidance document.	Does FDA agree that we have selected a reasonable predicate for our new technology?
What are the most recent review timelines for De Novo applications?	Does FDA agree that this Real-World Evidence supports our added clinical claim?
How does FDA regulate Quality Systems and how do I demonstrate compliance?	Is standardized testing sufficient to support our product's Indications for Use?

In summary:

Questions about FDA's regulation of medical devices?

- ✓ contact DICE.

Questions about FDA's regulation of *your* medical device?

- ✓ request a Q-submission meeting.

Check out this 2-minute video for more about the Division of Industry and Consumer Education!

- https://www.youtube.com/watch?v=yWYlO_4D4h4

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