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FDA Consultation Procedures

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Medical device manufacturers seeking to market their products in the United States must comply with regulatory requirements established by the U.S. Food and Drug Administration (FDA). In addition to selecting an appropriate premarket pathway (e.g., 510(k), PMA, De Novo, HDE), companies often benefit from seeking early consultation or feedback from the FDA. Below are the primary mechanisms and pathways through which organizations can engage with the FDA, along with an overview of the main marketing routes for medical devices.

Did you know?

The pre-Investigational Device Exemption (IDE) program, established in 1995, allowed sponsors to get FDA feedback on IDE applications before submission. Over time, the pre-IDE program evolved to include feedback on Premarket Approvals (PMAs), Humanitarian Device Exemptions (HDEs), De Novo requests, and 510(k) submissions. In 2014, the FDA implemented the broader Q-Submission Program, which formalized these interactions as "Pre-Submissions".

Q-Submission Program

The FDA's Q-Submission Program provides a structured way for manufacturers to request feedback before formal marketing applications, helping clarify regulatory expectations and streamline submissions. Early use of this program can prevent major deficiencies, keeping product development aligned with FDA expectations on testing and documentation.

The following table shows the different types:

Q-Sub types	Description	FDA feedback method	Timeframe for Feedback/Meeting *(from submission receipt)*
Pre-Submission	Formal request for comments through which the FDA helps guide product development and/or preparation of the authorization request (510(k), PMA, and De Novo).	Meeting with written feedback provided in advance.	Written Feedback: 70 or 5 days prior to meeting. Meeting: mutual agreement (day 70-75).
		Written Feedback Only	70 days
Submission Issue Requests (SIRs)	Request for feedback from the FDA to address issues communicated in a "hold letter" from a product application.	Meeting or Written Feedback	21 days *If SIR is received more than 60 days after FDA's marketing submission letter: 70 days
Study Risk Determinations	Request to the FDA to determine if a clinical trial is of significant risk, non-significant risk, or exempt from IDE regulations.	Formal Letter	90 days
Informational Meetings	The sponsor shares information with the FDA without expecting comments. This process is suitable if the sponsor wants to familiarize the FDA with a new product with unique technological innovations and is also useful to provide a development summary when multiple applications are planned.	Meeting	90 days

Other Non-Q-Sub Program Interactions of Interest:

There are other mechanisms, beyond the scope of the Q-Sub Program, through which industry can obtain information from the FDA. Two notable examples of such interactions include:

Request for Designation (RFD) and Pre-RFD process

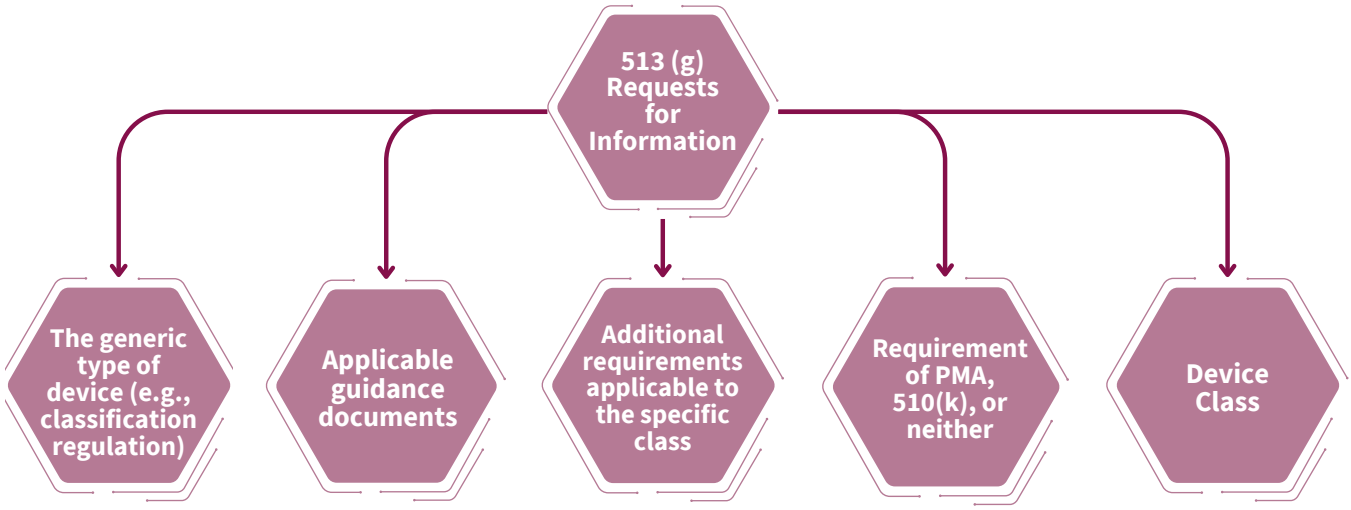
When there is uncertainty about whether a product qualifies as a medical device, combination product, drug, or biologic, a Pre-Submission Meeting may not be the most appropriate approach. In such cases, Requests for Designation (RFD) or Pre-Requests for Designation (Pre-RFD) may be more suitable. These processes help determine the correct regulatory pathway through the FDA's Office of Combination Products (OCP).

A Request for Designation (RFD) is a formal, binding, and more complex process used to determine the appropriate regulatory pathway through the FDA's Office of Combination Products (OCP). The FDA will provide a Designation letter within 60 days.

The Pre-RFD process provides informal, non-binding feedback on the regulatory identity or classification of a human medical product as a drug, device, biologic, or combination product. The FDA will issue a written preliminary classification and/or jurisdictional assessment within 60 days.

513(g) Requests for Information

Section 513(g) Requests for Information allow individuals to obtain FDA's views on a device's classification and applicable regulatory requirements under the FD&C Act. When a 513(g) Request for Information is submitted, the FDA will generally provide a written statement within 60 days detailing:



These requests do not address substantial equivalence, safety and effectiveness data, nor do they constitute device classification decisions or marketing approvals. Additionally, it is important to note that the 513(g) Request is subject to an associated fee.

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How can Asphalion help you?

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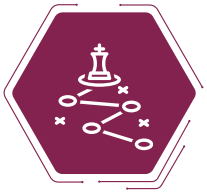
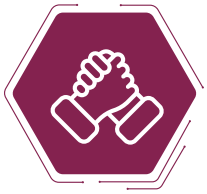
MedTech is the specialized division for Medical Device Regulatory Support within Asphalion.



Strategic Guidance
Develop comprehensive roadmaps and prepare De Novo classification requests.

Facilitate FDA Submission Process
Assist in compiling, organizing, and submitting the necessary documentation.

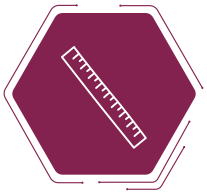
Engage in FDA Meetings
Accompany and represent the client in potential meetings with the FDA, ensuring all communications are effectively managed.



Post-Market Assistance
Provide ongoing support for compliance and regulatory requirements after the product launch.

Multidisciplinary team
Highly qualified personnel

Adaptability and confidentiality



Tailored services

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References to FDA guidelines:

- Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program. Guidance for Industry and Food and Drug Administration Staff. U.S. Food and Drug Administration. Published June 2, 2023.
- FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act. Guidance for Industry and Food and Drug Administration Staff. U.S. Food and Drug Administration. Published August 23, 2024.

Need help? Contact us!

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