

US

# Early Communication with the FDA

Guidelines on FDA correspondence for manufacturers developing  
and marketing medical devices in the US



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The FDA is a huge organization, and whether you are a small start-up company developing your first device or a large corporation expanding your product offerings, it's common to be at a loss when it comes to communicating with the FDA. And let's face it, sometimes it can be intimidating! This paper is intended to provide guidelines, tips, and other information to help you feel more confident in corresponding with the FDA when you need to obtain information regarding the development and marketing of your medical device.

## When is it appropriate to contact the FDA?

There is no right or wrong answer to this question. Part of the mission statement of the Center for Devices and Radiological Health (CDRH) is to "... facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways..." Therefore, CDRH is theoretically open to having dialogue with device developers and manufacturers to facilitate public access to safe, effective, and high-quality medical devices.

So the simple answer to the question is that it is appropriate to contact the FDA whenever you have a question to which you cannot find an adequate answer. The catch is that the FDA expects you to do your research first – utilize the [FDA device databases](#), "[CDRH Learn](#)," [guidance documents](#), and other sources on the [CDRH website](#) - prior to reaching for the phone. If you're still stumped and cannot find an adequate answer, then is the time to reach out to someone at the agency.



## Why should you contact the FDA?

This goes hand-in-hand with the question of “When.” Manufacturers often proceed down the development pathway without seeking FDA’s input, only to find that their 510(k) or IDE submission is woefully inadequate, or even that their product is not classified as a device at all! To avoid that unfortunate situation, it is advisable to seek FDA’s input when you have uncertainties and you haven’t been able to address them on your own. Even when you may think you have all the answers, there are times when it makes sense to obtain FDA’s guidance. Some examples of scenarios that should prompt contact with the FDA include:

- Early in the development of a novel device or combination product to ensure the correct classification;
- Prior to conducting animal studies to support premarket clearance or an IDE clinical study;
- Needing clarification about standards, guidance documents, or test methodologies that may apply to your device;
- Before proceeding too far into the development of a clinical investigation plan.



Once you’ve decided you need assistance from the FDA, the next question is: “Who should you contact and how do you contact them?” FDA has established the [Division of Industry and Consumer Education \(DICE\)](#) within the CDRH. DICE consists of former FDA investigators, Office of Device Evaluation (ODE) reviewers, and other specialists whose purpose is to provide technical and regulatory assistance to the medical device industry. This assistance includes a wide range of topics and concerns -- from design controls to post-market studies; from establishment inspections to standards; and from import requirements to Quality System Regulations (QSR). Therefore, DICE is an excellent point of first contact for general questions and if you haven’t yet established a relationship with an applicable reviewer or other relevant FDA staff.

Other sources for FDA contacts include the following, accessible from the FDA website:

- [‘Contact FDA’ webpage](#)
- [Small Business Contacts](#)
- [CDRH Management Directory](#)

In addition, the introduction at the top of each FDA guidance document contains the name and phone number (and usually email address) of the primary FDA contact person responsible for that guidance document. Therefore, questions specific to the content of an applicable guidance document (e.g., testing, labeling, conformance standards) may be addressed to the specified contact person. Of course, if you have initiated communication with someone in the device branch or division with jurisdiction over your device, you may call or email that person directly.

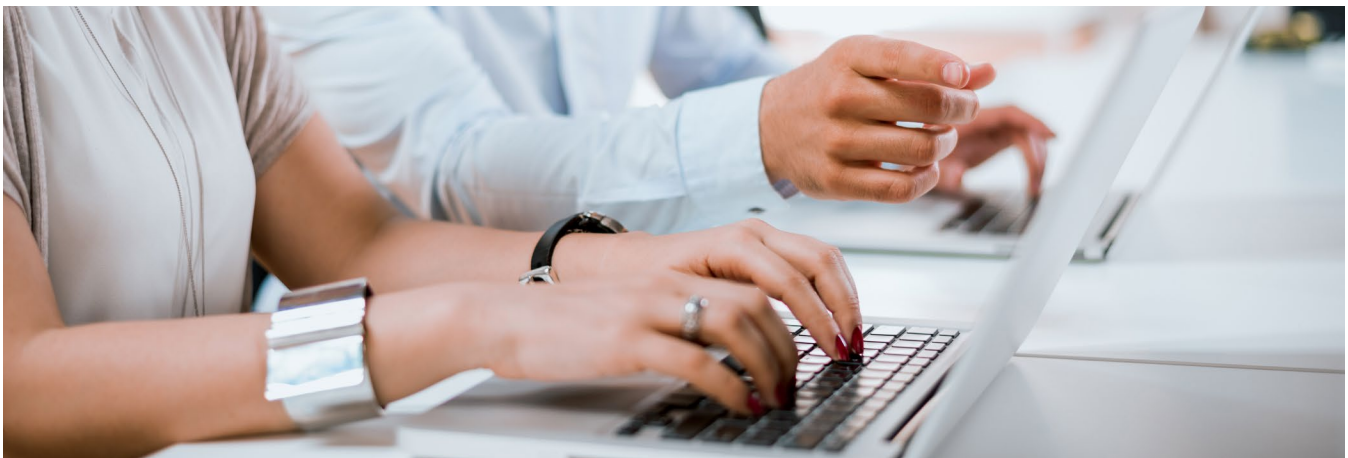
The above information and informal modes of contacting the FDA are primarily recommended for general questions. However, for many devices, at some point in the development and premarket lifecycle, the manufacturer will need to obtain more comprehensive input and advice from the FDA to move forward with a high degree of assurance. To facilitate those types of communication, the FDA has provided guidance documents that describe the process of contacting the FDA for feedback. We will delve into two of these guidance documents:

1. *Guidance for Industry and FDA Staff - [FDA and Industry Procedures for Section 513\(g\) Requests for Information under the FD&C Act](#) (April 2012);*
2. *Guidance for Industry and FDA Staff - [Requests for Feedback on Device Submissions: The Pre-Submission Program and Meetings with FDA](#) (February 2014)*

The guidance document on Section 513(g) Requests for Information (“513(g)”) establishes procedures for manufacturers to submit information to the FDA, and for the FDA to review and respond in writing regarding the device classification or the requirements applicable to a device under the Federal Food, Drug, and Cosmetic Act. In particular, the FDA can provide the following in response to a “513(g) Request”:

- Assessment of the generic type of device
- The particular class of device
- The type of premarket submission required
- Whether a guidance document is available for the device type
- Additional FDA requirements for the device type

The guidance document on the Pre-Submission Program and Meetings with the FDA provides instruction on contacting the FDA for feedback regarding medical device Investigational Device Exemption (IDE) applications or premarket submissions, such as Premarket Notification (510(k)) submissions, Premarket Approval (PMA) applications, and Evaluation of Automatic Class III Designations (*de novo*). This guidance document provides information regarding the logistics for the submission, receipt, review of, and response to these requests. Such requests for feedback are designated with a “Q” number and hence are often referred to as “Q-Subs,” as well as “Pre-Subs.”



Via the Pre-Sub program, a manufacturer may request a face-to-face meeting with the FDA at the agency's Washington DC offices, a teleconference, or even an email response, depending on the type of device and complexity of the issues and questions. A Pre-Sub meeting is highly recommended before conducting clinical, animal, or analytical studies or a marketing application for the following situations:

- The device involves a novel technology
- The device is for a "first of a kind" indications for use
- The regulatory strategy is not well established
- To obtain guidance on specific issues on study protocols (e.g., bench, animal, clinical)
- For a multiplex IVD or one with a new analyte, reference method, or unclear predicate
- To obtain feedback on clinical data collected in OUS studies
- To receive guidance on specific elements of a pending submission



Conversely, there are situations in which the Pre-Sub program is not an appropriate means of communication. For questions about non-specific device requirements, clarification about guidance document information, and similar questions of a general nature, it is advisable to contact DICE or a member of the applicable CDRH branch or ODE reviewer, as discussed previously. It is also not appropriate to submit a Pre-Sub request after a marketing submission has already been sent to the FDA. If the submission results in a finding of "not substantially equivalent" (NSE) or if you decide to withdraw the 510(k) to avoid an NSE result, you can then request a Pre-Sub meeting prior to submitting a new premarket submission. However, the FDA has implemented an option for a 'Submission Issue' meeting to discuss deficiencies with a 510(k) under review.

The title of the FDA Pre-Sub guidance document suggests that it deals strictly with Pre-Sub meetings and it is generally referred to as the "Pre-Sub" guidance. However, this document is comprehensive in that it also includes communication and feedback mechanisms for Informational Meetings, Study Risk Determinations, Formal Early Collaboration Meetings (i.e., Agreement and Determination Meetings), Submission Issue Meetings, and PMA Day 100 Meetings.

For a manufacturer developing a truly novel device or one with a familiar design but for a completely new intended use, it may be beneficial to communicate with the FDA early in the process strictly with the intent to inform them of the plans to bring this new device type to the US market. This is done by requesting an “Informational Meeting” with the FDA in order to share or educate them about your new technology. Although rarely utilized, this type of meeting can be valuable in order to engage FDA’s mindset early and to prepare them for future meetings regarding classification and submission requirements. If conducted properly, it also sets the stage for familiarity and collaboration for what is likely to be a long-term relationship.



Manufacturers developing novel devices should communicate with the FDA early to request an Informational Meeting.

## Conclusions

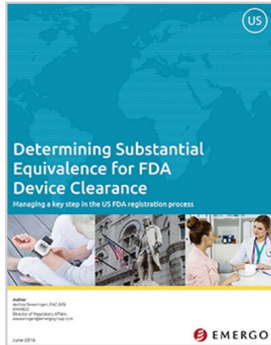
So, there are many avenues to contact and establish ongoing communication with CDRH, whether to simply share information or to request feedback on complex concerns. Over the past several decades, the FDA has swung between operating primarily as an enforcement organization and as an agency open to engaging the medical device industry. Thankfully, although the regulatory environment constantly evolves, the FDA pendulum seems to currently be on the side of openness and collaboration with industry. In order to help maintain this culture, I leave you with these simple words of advice for communicating with the FDA:

- DO your homework before contacting the FDA (their website has a wealth of information).
- DO provide them with adequate information in order to facilitate effective and accurate feedback.
- DO be clear and concise about what you need (ask specific, relevant questions).
- Do NOT become a pest/DO be respectful of their time (build a favorable relationship).
- Do NOT expect the FDA to answer every question in the detail you would like (the FDA is not an R&D or regulatory consultant group).
- Do NOT go it alone. If you don’t have existing in-house regulatory expertise, engage a knowledgeable third party to assist you in your communications and meetings with the Agency.



### About the Author

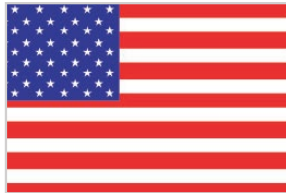
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## Learn more about FDA clearance for medical devices

If you enjoyed this white paper, we know you will like our white paper about determining substantial equivalence for FDA medical device clearance. We discuss predicate devices, how to establish and demonstrate equivalence, an overview of FDA 510(k) preparation, and more.

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## Need help with US FDA compliance?

Emergo helps medical device companies with regulatory compliance and market access in the USA and markets worldwide. Here's how we can help:

- Device and IVD classification and assessment
- FDA QSR implementation and audits
- FDA 510(k) preparation and submission

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