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Pre-Submissions 510(k) and the FDA

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Q-Submissions (Q-Sub)

Overview and general information

The **Q-Submission (Q-Sub) Program** offers medical device manufacturers the opportunity to engage in collaborative discussions with FDA review teams throughout the product development process.

There are several types of Q-submissions, including:

Pre-submission

Formal request for comments through which the FDA helps guide product development and/or the preparation of the application.

Informational meetings

The sponsor shares information with the FDA without expecting comments; the FDA will be in "listening" mode. This is appropriate if the sponsor wants to familiarize the FDA review team with a new device that has significant technological differences from current devices. It is also useful for providing an overview of development when multiple submissions are planned.

Study risk determination

Request the FDA to determine if a clinical study is of significant risk, non-significant risk, or exempt from IDE regulations.

Submission Issue Request

Request for FDA feedback to address issues communicated in a hold letter from a marketing application.

Pre-Submissions are the original and most common type of Q-Submission; they allow companies to receive guidance from FDA review teams prior to a premarket submission (i.e. 510(k), PMA) or IDE.

Pre-Submission Application

Company sponsors may reference the Q-Submission Program Guidance Document and the Refuse to Accept (RTA) checklist to confirm a Pre-Submission application contains all necessary components:

- Cover letter
- Device description
- Intended use
- Agenda, attendees and mode of meeting (if meeting is requested)
- Questions to FDA
- Non-clinical or clinical reports (if applicable)

An applicant may request a Written Feeback Only or a Written Feedback + Meeting.

Although optional, Pre-Submission meetings:

- May help to expedite review times and shorten regulatory pathways for innovative technologies.
- Enable applicants to initiate communication, build a relationship with FDA review teams, and gain insight into the FDA's expectations for the product.
- Are held either in-person or via conference call with FDA review teams, first line managers, and other FDA staff.

Pre-RFD and PFD

In case of doubt of whether your product is a medical device, a combination product, a drug or a biologic, a Pre-Submission may not be the right fit for you.

Requests for Designation (RFD) (formal, binding, more complex) and **Pre-Requests for Designation** (Pre-RFD) (simple, nonbinding, informal) may be the appropriate pathway. These processes help facilitate the determination of the appropriate regulatory pathway with the FDA's Office of Combination Products (OCP).

- The sponsor can approach the FDA Office of Combination Products (OCP) to clarify on the classification of a product.

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513(g) Request for Information

While not a Pre-Submission or Informational meeting, a 513(g) Request for Information allows medical device manufacturers to inquire about their products' class and corresponding regulatory requirements, and proposed labelling. Section 513(g) governs requests "for information respecting the class in which a device has been classified or the requirements applicable to a device under [the] Act." See FDA guidance on the subject.

Process and timelines

Note: The applicant must prepare and submit the minutes.

510(k)

510(k)

Some Class I products, **most of Class II** and some Class III require a 510(k).

- The purpose of a 510(k) is to demonstrate that a new or modified device is **"substantially equivalent"** to a **"predicate device"**.
- A predicate device is a legally marketed device that is **cleared/authorised on the market by a 510(k)**.
- Product families can be authorised in a single 510(k) such as catheters of various sizes, if:
  - they share indications for use
  - they share technological characteristics
  - safety and effectiveness issues are essentially the same within the family

Predicate Search

1) Select most appropriate Classification Panel
2) Select most appropriate Subpart
3) Search Product Codes under this subpart
4) Search MDs cleared under these Product Codes.
5) Access the Decision Summaries to check-out 510(k) data

Medical Specialty		Regulation Citation (21CFR)
73	Anesthesiology	Part 868
74	Cardiovascular	Part 870
75	Chemistry	Part 862

PART 870 -- CARDIOVASCULAR DEVICES
Subpart E--Cardiovascular Surgical Devices

Sec. 870.4450 Vascular clamp.

(a) Identification. A vascular clamp is a surgical instrument used to occlude a blood vessel temporarily.
(b) Classification. Class II (performance standards).

1 to 3 of 3 results
510(k) Cardiovascular 870.4450

Results per page 5

New Search | Export to Excel | Help

Product Code	Device		Regulation Number	Device Class
MJN	Catheter, Intravascular Occluding, Temporary	Vascular Clamp	870.4450	2
DXC	Clamp, Vascular	Vascular Clamp	870.4450	2
NMF	Clamp, Vascular, Reprocessed	Vascular Clamp	870.4450	2

1 to 10 of 79 Results
ProductCode: MJN Decision Date To: 06/30/2019

1 2 3 4 5 6 7 8 >

Results per Page 10

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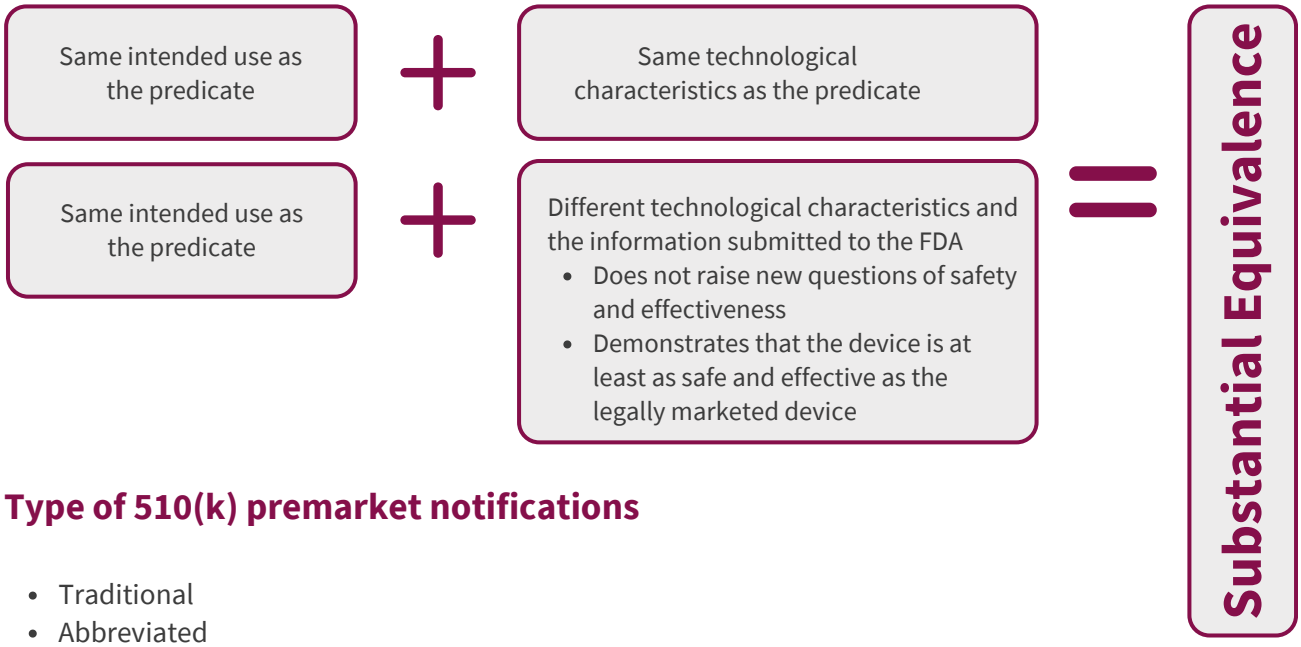
Device Name	Applicant	510(K) Number	Decision Date
Eclipse 2I	Balt USA, LLC	K183045	04/30/2019
Occlusion Balloon Catheter	QXMedical, LLC	K183679	04/24/2019
Pruitt F3 Carotid Shunt, 10 Fr, Pruitt F3 Carotid Shunt, 9 Fr, Pruitt F3 Carotid Shunt, 8 Fr	LeMaitre Vascular	K182916	11/16/2018
Sniper Infusion Catheter With Balloon Occlusion	Embolx, Inc	K180904	06/08/2018
Gore Molding And Occlusion Balloon Catheter	W.L Gore And Associates Inc	K172567	01/31/2018
Er-Reboa Catheter	Prytime Medical Devices, Inc.	K172790	11/08/2017



Type of 510(k) premarket notifications

- Traditional
- Abbreviated
- Special

Traditional

Must submit the necessary elements included in 21CFR 807.87 which are the administrative requirements, such as the company name, trade name, etc.

The traditional 510(k) is based on the demonstration of substantial equivalence. It can be used under any circumstance.

Structure of Electronic Submission Template:

- Submission type
- Cover letter
- Applicant information
- Pre-submission correspondence and previous regulator interaction
- Consensus standards
- Device description
- Proposed indications for use
- Classification
- Predicates and substantial equivalence
- Design / special controls, risks to health, and mitigation measures
- Labelling
- Reprocessing / Sterility
- Shelf-life
- Biocompatibility and performance testing
- Software / firmware / Cybersecurity / Interoperability
- Electromagnetic Compatibility (EMC), Electrical, Mechanical, Wireless and Thermal Safety
- References

Abbreviated:

It is based on the use of documents which are

1. **Guidelines**
2. **Special controls**
3. **Recognised consensus standards**

Under certain conditions, applicants may not need to submit test data in an abbreviated 510(k).

*The sponsor provides **Reports** on the use of the guidelines and/or special controls or **Declarations of conformity** with the standards, to expedite their review in the application.*

Special

The Special 510(k) Program is intended to facilitate the submission, review, and clearance of a change to a manufacturer's own legally marketed predicate device ("existing device") that is already authorized for commercial distribution through 510(k) clearance, preamendments status, reclassification, or through a granted De Novo classification request.

For certain device changes, FDA believes that design control procedures can produce reliable results that can form the basis for a SE determination without compromising the statutory and regulatory criteria for SE.

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