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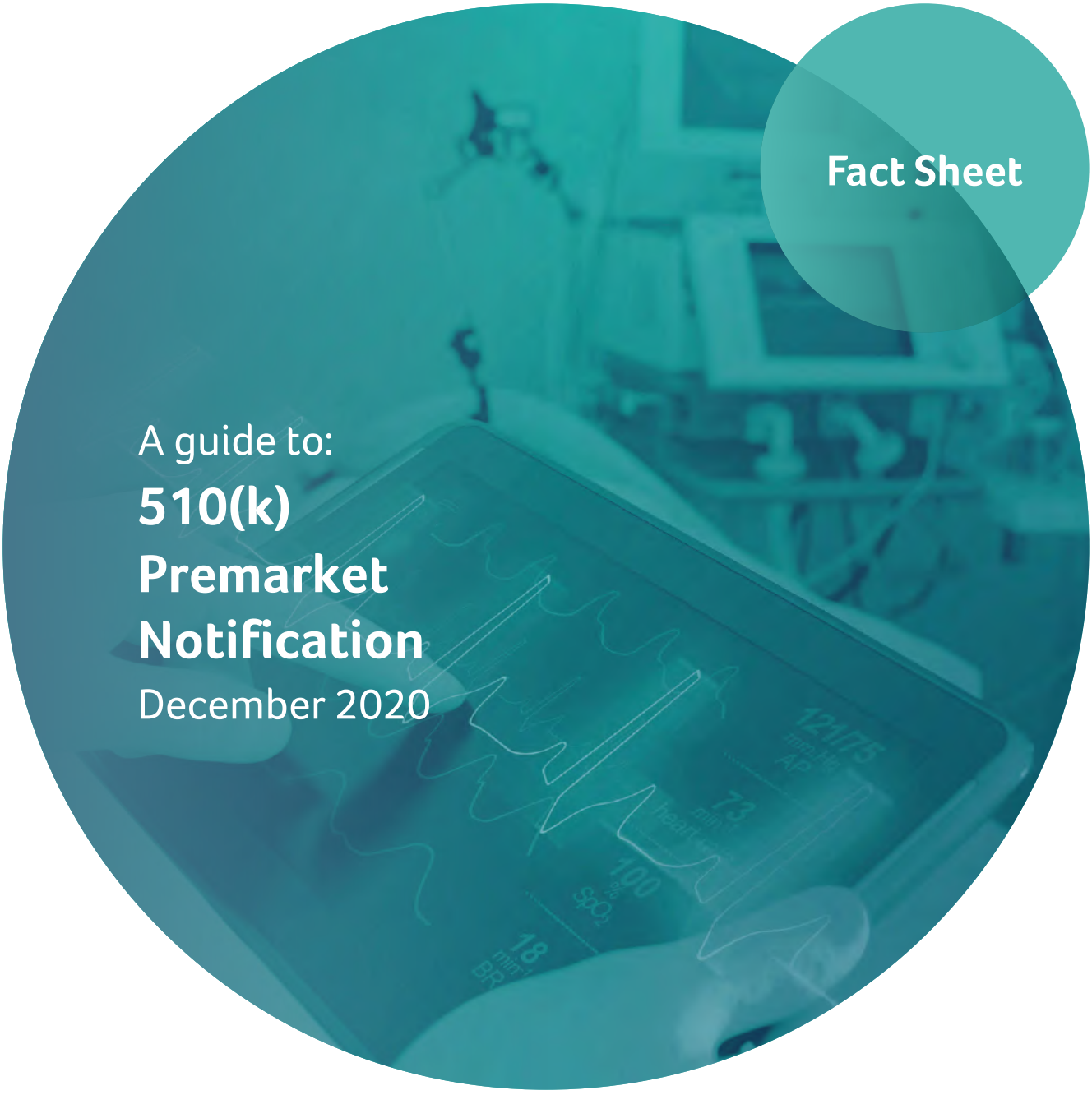

Fact Sheet

A guide to:

510(k) Premarket Notification

December 2020

Smart consulting,
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A guide to 510(k) Premarket Notification

Introduction

To market a Class I, II or III device intended for human use in the U.S., (for which a Premarket Approval application (PMA) is not required) you must submit a 510(k) to the FDA, unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Before marketing a device, each submitter must receive an order, in the form of a letter, from the FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order "clears" the device for commercial distribution.

This fact sheet covers the three types of Premarket Notification 510(k)s that may be submitted to the FDA:

- Traditional 510(k) submissions
- Abbreviated 510(k) submissions
- Special 510(k) submissions

The Special and Abbreviated 510(k) Programs were developed by the FDA in 1998 to facilitate the review of certain types of submissions subject to 510(k) requirements. These Programs were previously described in The New 510(k) Paradigm guidance. In 2019, the FDA split The New 510(k) Paradigm into two distinct guidance documents:

- **The Special 510(k) Program**
- **The Abbreviated 510(k) Program**

When should you use each submission type?

Traditional 510(k)

A **Traditional 510(k)** is the most common type of 510(k).

The Traditional 510(k) Program can be used under any circumstances where you're seeking marketing authorisation of your device through the 510(k) Program.

FDA generally reviews Traditional 510(k) submissions within 90 days of receipt.

Abbreviated 510(k)

You may choose to submit an **Abbreviated 510(k)** when your device submission relies on:

- FDA guidance document(s)
- Demonstration of compliance with special controls for the device type, or
- Voluntary consensus standard(s)

FDA generally reviews Abbreviated 510(k) submissions within 90 days of receipt. If the FDA determines that your Abbreviated 510(k) is not appropriate for review as submitted, you will be notified of this decision, and your submission will be converted to a Traditional 510(k).

Special 510(k)

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 that is already authorised for commercial distribution through 510(k) clearance, when:

- The proposed change is submitted by the manufacturer legally authorised to market the existing device;
- Performance data is unnecessary, or if performance data is necessary, well-established methods are available to evaluate the change; and
- All performance data necessary to support substantial equivalence can be reviewed in a summary or risk analysis format.

FDA generally reviews Special 510(k) submissions within 30 days of receipt. If you submit a Special 510(k) that the FDA does not believe is appropriate for review under the Special 510(k) Program, the FDA will convert the submission to a Traditional 510(k) and notify you accordingly.

What`s involved in submitting a 510(k)?

What`s involved in the submission?

- There is no Premarket Notification 510(k) "form" for you to complete
- A 510(k) is a submission containing information required under 21 CFR 807.87
- All 510(k)s are based on the concept of substantial equivalence (SE) to a legally marketed device, also referred to as a predicate
- All 510(k)s need to provide a comparison between the device to be marketed and the predicate device or devices
- For more information on the regulatory framework, policies, and practices underlying the FDA's 510(k) review process, refer to the guidance **The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)]**

The fees for your 510(k) submission

Traditional, Special, and Abbreviated 510(k)s require the same user fee. The Fees for Fiscal Year 2021 (October 1, 2020 to September 30, 2021) are as follows:

Standard Fee

$12,432

Small business fee

$3,108

Preparing & Submitting your 510(k)

Step 1 - Find a Predicate Device

- Identify a primary predicate device which is most similar to the device you intend on submitting through the 510(k) Program in terms of indications for use and technological characteristics
- Under certain circumstances, you may claim substantial equivalence to more than one predicate
- FDA recommends that you identify the 510(k) number of the predicate device(s)
- Please refer to **How to Find and Effectively Use Predicate Devices** for additional guidance

Step 2 - Locate the applicable Guidance Documents

- FDA recommends that device-specific guidance documents be consulted during the device planning stage
- The FDA issues guidance documents to communicate its recommendations to the industry. These documents are available through the **FDA Guidance Documents page**
- The design control requirements (21 CFR 820.30) of the Quality System regulation should also be reviewed, and are available for quick reference **here**

Step 3 - Prepare your submission

In addition to the items required under 21 CFR 807.87 and 21 807.90, CDRH suggests that you refer to the FDA guidance document entitled, **"Format for Traditional and Abbreviated 510(k)s"** for the suggested format and content of a Traditional and Abbreviated 510(k).

For additional recommendations on content of a 510(k) submission, refer to the **Content of a 510(k)** and **510(k) Format Tips**

To facilitate the FDA`s review of the data, analysis, and conclusions in your application, you should ensure that you:

- Logically present the data
- Provide evidence of the scientific soundness of the test and data analysis
- Demonstrate the relevance of the test program to the device and the intended use
- Ensure completeness of the summary report of the tests or studies

Useful Tips

To help ensure that your application is complete make sure to:

- *Understand the FDA decision-making process by taking a look at: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)]*
- *Obtain and use the right guidance - FDA provides many device specific guidance documents for the preparation of marketing applications*
- *Use the CDRH Premarket Review Submission Cover Sheet and the Screening Checklist for all Premarket Notification 510(k) Submissions to prepare your submission. The cover sheet is a "fill-in-the-blank" format which satisfies many of the 510(k) requirements*

Preparing & Submitting your 510(k) (continued)

Step 4 - Prepare your submission

- Your 510(k) submission must be submitted in an electronic format (eCopy) - more guidance on this is available **here**
- Once your submission is received by the FDA, they do not return the submission or any copies to you, so you should retain a copy for your records
- Your medical device submission package should be sent to CDRH's or CBER's Document Control Center (DCC). The current mailing address for CDRH's DCC and a link to CBER's DCC's mailing address are available **here**
- Send your 510(k) to the FDA by registered mail with a return receipt or a commercial delivery service
- You should receive an acknowledgment of receipt from the FDA that includes the assigned 510(k) number

Step 5 - The approval process for Traditional & Abbreviated 510(k)s

DAY 1
FDA receives your 510(k)

BY DAY 2
FDA sends Acknowledgment Letter or Hold Letter (the latter if there are unresolved issues with your User Fee / eCopy)

BY DAY 15
FDA conducts Acceptance Review
You will be informed if your 510(k) has been accepted for Substantive Review or placed on RTA Hold

BY DAY 60
FDA conducts Substantive Review
You will be informed via a Substantive Interaction on whether your submission will proceed to Interactive Review, or will be placed on hold pending provision of Additional Information

BY DAY 90
FDA sends final MDUFA Decision on your 510(k)

BY DAY 100
If MDUFA Decision is not reached, FDA provides Missed MDUFA Decision Communication that identifies outstanding review issues

Text source:
https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k