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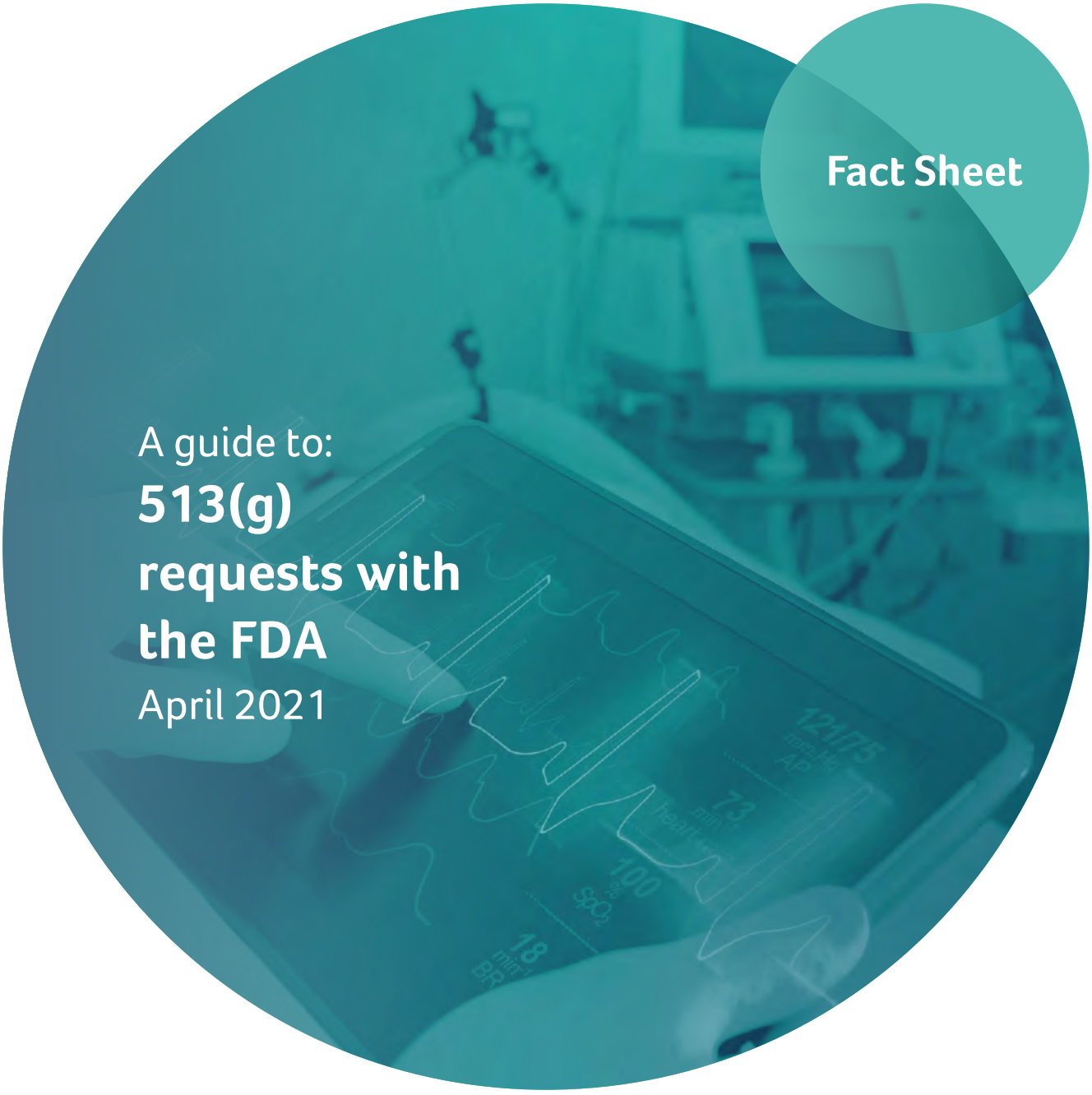

Fact Sheet

A guide to:

513(g) requests with the FDA

April 2021

Smart consulting,
enhanced medical solutions.

What is a 513(g) request for information?

Introduction

A 513(g) request is a means for medical device manufacturers to obtain information about the FDA's views regarding the classification and regulatory requirements for a particular product.

Should you require information regarding the **class in which your device has been classified, or the requirements applicable to the device,** then you can submit a written request to the FDA. The FDA will typically provide a written reply regarding the classification of your device and the associated regulations within 60 days.

A 513(g) request can also be submitted to:

- **Ascertain whether you need to submit a 510(k) if you intend on modifying your device.**
- **Determine the least cumbersome mechanism to get your device approved.**

Submitting your 513(g) request

A 513(g) request for information submission should be identified as a **"513(g) Request for Information"**. One electronic copy (eCopy) or one complete paper copy of the request should be sent to the current address found here for devices regulated by CDRH, or here for devices regulated by CBER.

The User fees for your 513(g) request

Standard Fee	Small business fee
$4,936	$2,468

Click here for more information on user fees.

What to include in your 513(g) request

Your 513(g) request for information should contain the following:

A cover letter that identifies your request as a "513(g) Request for Information" and includes:

- The date of the request
- The name of your device
- Your specific question(s) concerning the class in which your device has been classified and/or the regulatory requirements applicable to your device
- The requestor's name, address, telephone number, fax number, & email address
- The 513(g) requestor's signature

A description of your device that includes:

- A list of materials and components used in/with your device
- Photographs, engineering drawings, and/or samples of your device
- A summary of your device's operational principles
- A description of the type and amount of energy to be used or delivered by your device
- A description of similar devices in commercial distribution in the US, if available

A description of what your device is to be used for, including the following information:

- The disease/condition with respect to which your device is to be used
- Prescription versus over-the-counter use
- Part of the body/type of tissue applied to/interacted with
- Frequency of use
- Physiological purpose (e.g., removes water from blood, transports blood, etc.)
- Patient population
- Any other labelling information related to the patient use of your device

Labelling or promotional material for your device including:

- Any proposed labelling or promotional material for your device
- Any labelling or promotional material of a similar, legally marketed device
- If no proposed labelling is available for the described device or for a similar legally marketed device, this should be noted in your cover letter

Receiving a response to your 513(g) request

The FDA's response will be relative to the questions posed in the 513(g) request, and typically they respond within 60 days of receipt. Responses will generally fall into one of the following scenarios, based solely on the information provided in your 513(g) Request for Information.

Scenario 1 | Your device is a device within the meaning of section 201(h) of the FD&C Act

- It appears to be an unclassified pre-amendments device type and therefore is subject to the **510(k)** requirement
- It appears to be a post-amendments device type that has not yet been reclassified and therefore is subject to the **PMA** requirement
- It appears to be a device that is a classified device type. The FDA will generally identify the generic device type and the class of device that your product falls within, plus the type of submission required to market devices of that particular class within that generic type e.g.:
    - Class I or II subject to the 510(k) requirement;
    - Class I or II exempt from the 510(k) requirement;
    - Class III subject to the 510(k) or PMA requirements

Scenario 2 | Your device is not a device

- It may be another type of product regulated by FDA. In this case, the FDA would provide you with contact information for another component within the FDA
- It appears not to be a product for which the FDA has jurisdiction

Scenario 3 | Your device is a combination product

- It is a combination product where it is not clear which Centre has primary jurisdiction
- To discuss the assignment of your product further, you should contact the **Office of Combination Products**

Scenario 4 | Your request for information is incomplete

- If your 513(g) request is incomplete and the FDA is unable to provide information regarding classification and/or applicable requirements because you have not submitted sufficient information, you will be contacted with a request for additional information
- You should respond to the request within 30 days, otherwise your 513(g) will be withdrawn and you will be issued with a notice of withdrawal from the FDA