

Elements of a Quality 510(k) Submission

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DHT6B: Division of Spinal Devices

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Learning Objectives



1. To understand a 510(k) submission and what should be submitted to the FDA
2. Common FDA asks that can be eliminated with proper information presentation
3. Organizing information in a way that is concise and readily available for review
4. AINN responses; information presentation and situations where interactive review is beneficial to avoid unfavorable decisions



510(k) for Medical Devices



- A Premarket Notification for Class II – Moderate Risk Devices that are subject to general and special controls
- Section 510(k) of the Federal FD&C Act 21 CFR 807 Subpart E
- Allows FDA to determine Substantial Equivalence



Substantial Equivalence (SE)

Demonstration that a new device, as compared to a predicate device, has:

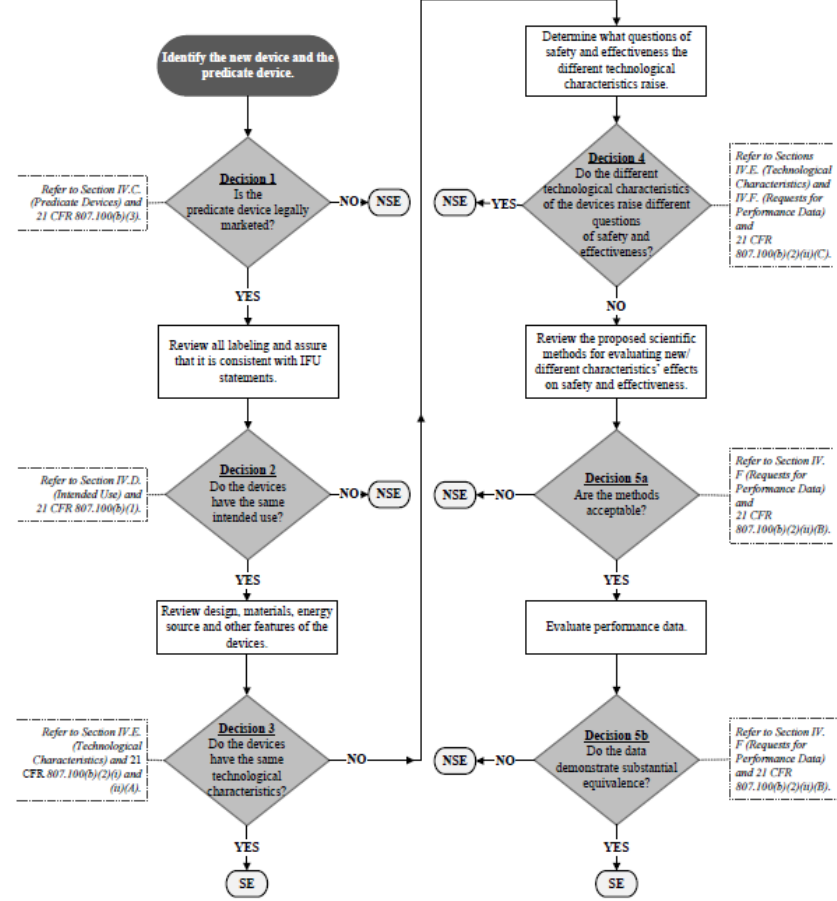
- the same intended use and
- the same technological characteristics, Or differences in technological characteristics do not raise different questions regarding safety and effectiveness



Substantial Equivalence (SE)



Appendix A. 510(k) Decision-Making Flowchart



SE = "Substantially Equivalent"
 NSE = "Not Substantially Equivalent"
 IFU = "Indications For Use"

This Flowchart is not intended to be used as a 'stand-alone' document and should only be considered in conjunction with the accompanying text in this guidance.



Specific Sections of a 510(k) Submission

Sections that will be covered in more detail during other (previous/upcoming) presentations:

- Device Description
- Indications for Use
- Sterilization/Reprocessing/Packaging
- Biocompatibility
- Mechanical Testing



Specific Sections of a 510(k) Submission

Sections that will be discussed in this presentation:

- Purpose and History
- 510(k) Summary/Statement
- Comparison of Technology to a Predicate Device
- Labeling



Specific Sections of a 510(k) Submission

Purpose and History

- Describe the purpose of the submission
- Special considerations and/or characteristics particular to your device
- Provide information if you have any similar devices in your portfolio, irrespective of the regulatory outcome



Specific Sections of a 510(k) Submission

510(k) Summary/Statement

- A 510(k) Summary or Statement per 21 CFR 807.92 or 21 CFR 807.93, respectively
- Please only provide one; Summary or Statement
- Summary should be in a separate section
- Indications for Use should be same as provided in labeling and Indications statement
- Identify ONE primary predicate; You can have multiple additional predicates, as well as reference devices, but these are not always necessary
- Brief discussion of the tests submitted
- Conclusion



Specific Sections of a 510(k) Submission

510(k) Summary/Statement

Things Not To Do/Provide

- Include Confidential notation
- Deviate from the recommended format and verbiage
- More information than prescribed OR necessary for a determination of substantial equivalence



Specific Sections of a 510(k) Submission

Comparison of Technology to a Predicate Device

- Comparative images, if available
- Comparison of device design, size, features and technology to a valid predicate
- These comparisons can be summarized in a tabular format; with supplemental in-depth discussions



Specific Sections of a 510(k) Submission

Comparison of Technology to a Predicate Device

- A well organized table comparing the new device to the identified predicate
- This comparison should include but not limited to:
 - ✓ Indications for Use
 - ✓ Technological characteristics – Device design, shape, size/dimensions, material, manufacturing, post-processing and any other important aspects of your device

For each identified difference, provide proper explanations.



Specific Sections of a 510(k) Submission

Comparison of Technology to a Predicate Device

	Subject Device	Predicate Device	Reference Device
Image			
Material			
Length (M-L)			
Width (A-L)			
Height			
Lordosis			
Minimum Graft Area			



Specific Sections of a 510(k) Submission

Comparison of Technology to a Predicate Device

- Include discussion and rationale for subject device that are outside the range of sizes of the cited predicate device
- Discuss the relevance of cited additional or reference devices in addressing these differences
- If citing literature, please be specific to the relevance



Specific Sections of a 510(k) Submission

Labeling (Label)

- Please provide labels for device and device specific instruments
- List all device material/s on the label
- Provide a statement referring to package insert for labeling limitations



Specific Sections of a 510(k) Submission

Labeling (Surgical Technique Manual)

- Magnified sketches of important steps
- Removal/revision procedures
- Indications, and that they are same as rest of the submission



Specific Sections of a 510(k) Submission

Labeling (Package Insert)

- MR Language

The [Device] has not been evaluated for heating or migration in the MR environment.

Additionally, please do not include any claims that are not pertinent to a determination of substantial equivalence



Specific Sections of a 510(k) Submission

Organization

- Table of Contents
- Description sections respective to the table
- Name and organize your files in a way that indicates their contents
- Have a distinctive name that gives an indication of the content
- Follow a consistent pattern
- Avoid repetition of elements and information



Specific Sections of a 510(k) Submission

Organization

- Do not forget the basics when presenting your information
 - Readability
 - Avoid repetitive information
 - Consistent font and format
 - Keep it simple
 - Proofread your submission



AINN Response

The best way to response to the AINN request is in a Q & A format; followed by appropriate appendices for detailed information

➤ Deficiency 1

1. Please modify the labeling to include the following:
 - a. Please add the trade name “XYZ” to the package label.
 - b. Please specify the type and grade of PEEK used (e.g. FDA OHT6 6B-1) in the package label, package insert, and surgical technique.



AINN Response

The best way to response to the AINN request is in a Q & A format; example follows:

➤ Deficiency 1 Response

1. Labeling information has been modified to include the following:
 - a. Trade name “XYZ” is added to the package label. Please refer to Appendix A1, Section 1, for updated package label. Clean and redlined versions are provided in Section 2 and 3 respectively of Appendix A1.
 - b. PEEK grade, FDA OHT6 6B-1, is specified in the updated package label, package insert, and surgical technique. Please refer to Appendix ... Clean and redlined versions are provided in Section ...



AINN Response

In situations where the deficiency is not clear or you would like to provide an alternate approach

- Get clarity
- Get in touch with the reviewer
- Discuss your proposed answer/approach



AINN Response

- AINN response could be deemed incomplete, if all outstanding issues are not explicitly addressed

We are only an e-mail/phone call away

Thank You!

