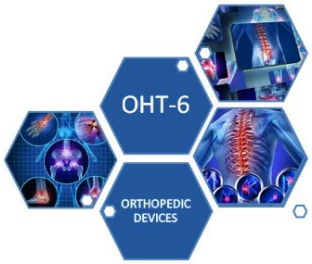


U.S. FOOD & DRUG ADMINISTRATION

Device Description and Indications for Use Statement:

Clear Yet Concise is Best

Colin O'Neill, MBE
Assistant Director (Acting)

Charles H. Warner, MS
Lead Reviewer

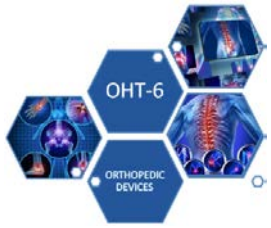
Extracolumnar Spinal Devices Team

DHT6B: Division of Spinal Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

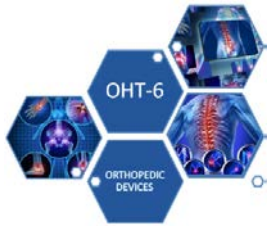


Outline

Requirements to Consider

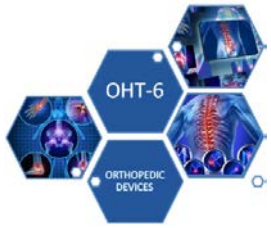
- Device Description
  - RTA Elements
  - FDA Guidance and Classification Regulation
  - Clear Yet Concise Highlights

- Indications for Use
  - RTA Elements
  - FDA Guidance and Classification Regulation
  - Clear Yet Concise Highlights

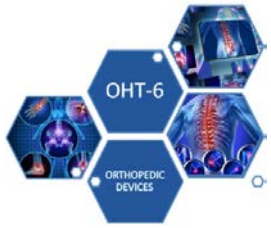


Requirements to Consider

- RTA checklist elements
- FDA Guidance Documents
  - The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]
  - Spinal System 510(k)s
  - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device
- Spinal device regulations
  - 21 CFR 888.3050: Spinal interlaminal fixation orthosis
  - 21 CFR 888.3060: Spinal intervertebral body fixation orthosis
  - 21 CFR 888.3070: Thoracolumbosacral pedicle screw systems
  - 21 CFR 888.3075: Posterior cervical screw systems
  - 21 CFR 888.3080: Intervertebral body fusion devices



Device Description



FDA Guidance: The 510(k) Program

Key Characteristics to Provide

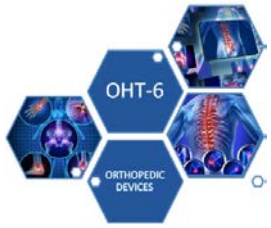
- An overall description of the device design
  - Engineering drawings or other figures
  - Diagram identifying how multiple components work together
  - Discussion of physical specifications, dimensions, and design tolerances
  - Clear purpose of design and intended use for significant device features
- Materials
  - Complete identification of detailed chemical formulation
  - Identification of any additives, color additives, coatings, or any surface modification
  - Identification of material processing and/or state
- Energy sources (if applicable)
- Other key technological features (if applicable)
  - Software/hardware
  - Porosity, degradation characteristics, etc.

510(k) RTA Checklist Element 12

12. The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.

    a. The submission addresses device description recommendations outlined in the device-specific guidance.

    b. The submission includes device description information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device.



Device-Specific Guidance: Spinal System 510(k)s

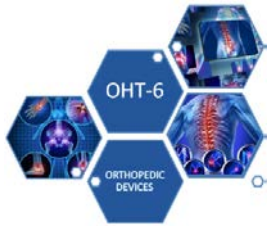
Scope of Spinal System 510(k)s Guidance

- Included: Plate and rod-based spinal systems for fusion, vertebral body replacements
- Excluded: Facet screws, interbody fusion devices (i.e., cages), non-fusion devices (e.g., disc replacements, interspinous process spacer)

Purpose of Your 510(k)

Clearly state the purpose of the 510(k):

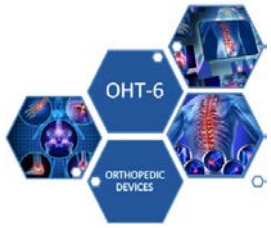
- new spinal system
- modifying or adding new component(s) to a cleared spinal system
- revising indications for use statement
- change in materials, sterilization, reprocessing, shelf-life, etc.
- other modifications



Device-Specific Guidance: Spinal System 510(k)s

Specific Device Description Information

- a table of components
- complete, dimensioned engineering drawings of each subject component
- a written description of the individual components and how the subject components interconnect (e.g., diameter of rods, sizes of screws, size/thickness of anterior plates, geometry of vertebral body replacement, type of screw/rod interconnection). Supporting sketches and/or photographs of the interconnection mechanisms may be useful
- a comparison of the largest profile of the device compared to a predicate device (if the device is implanted anteriorly or anterolaterally)
- a magnified photograph and/or sketch of the spinal system attached to a spinal model



Device-Specific Guidance: Spinal System 510(k)s

Specific Device Description Information Continued

- identification of the materials from which the subject components are manufactured and any voluntary material standards to which these materials conform

- information on the surgical instruments considered unique to the implantation of the subject system (i.e., list of surgical instruments, photograph(s)/drawing(s) of each, identification of materials from which they are manufactured, and any voluntary material standards to which these materials conform)

Device-Specific Guidance: Spinal System 510(k)s

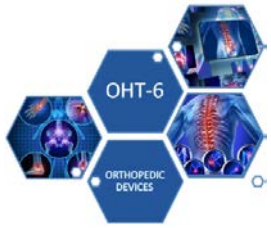
Table of Components

All-inclusive list of components previously cleared (if applicable) and those under review for the given spinal system, highlighting the components that have been added.

Table 2. Sample Table of Components

Component Name	Part Number	Sizes (lengths and diameters)	Levels of Attachment	510(k) number[A]
Offset sacral screw	xx.xxx	XXmm-XXmm	L1-L5	KXXXXXX

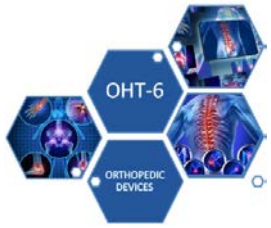
[A] 510(k) in which component was cleared as part of the subject system or identification of the component as new



Special Controls Guidance: Intervertebral Body Fusion Device

Intervertebral Body Fusion Device Descriptive Information

- a written description of the device
- its indications for use
- a table of device sizes and geometries
- complete, dimensioned engineering drawings of each subject device component
- identification of the materials from which the subject components are manufactured and any voluntary material standards to which these materials conform
- a magnified photograph and/or sketch of the intervertebral body fusion device attached to a spinal model

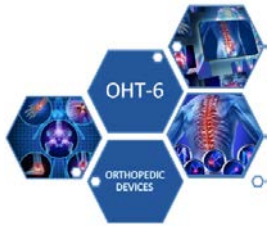


Special Controls Guidance: Intervertebral Body Fusion Device

Device-specific (unique) Instrument Description Information

- the trade name and functional description
- photographs or drawings
- the material composition
- any material standards met
- any previous clearance

If your instrument is exempt from the 510(k) requirements of the act, indicate its classification regulation (e.g., 21 CFR 888.4540).



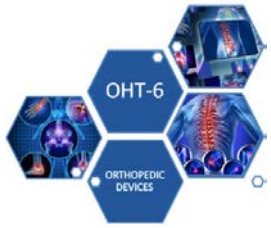
Special Controls Guidance: Intervertebral Body Fusion Device

Material Characterization

- Describe all material components of the device
- Identify the source and purity of each component. Alternatively, submit a Certificate of Analysis (CoA) or Materials Safety Data Sheet (MSDS) or reference a Device Master File if include the appropriate letter of cross reference

Polymers (final sterilized material)

- information describing leachables
- material properties
- molecular weight
- molecular weight distribution
- chemical and crystal structures
- percent of crystallinity
- degree of cross-linking of that polymer



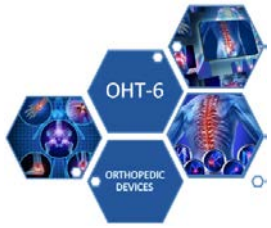
Special Controls within Device-Specific Classification Regulation

21 CFR 888.3070: Thoracolumbosacral pedicle screw systems

- (b)(2)(i): "The design characteristics of the device, including engineering schematics, must ensure that the geometry and material composition are consistent with the intended use."

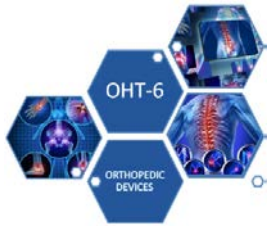
21 CFR 888.3075: Posterior cervical screw systems

- (b)(1): "The design characteristics of the device, including engineering schematics, must ensure that the geometry and material composition are consistent with the intended use."



510(k) RTA Checklist Element 13

13. Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).



510(k) RTA Checklist Element 14

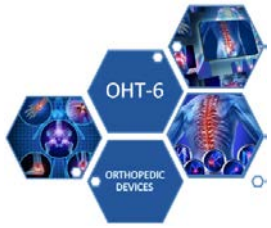
14. The submission includes descriptive information for the device, including the following:
    a. A description of the principle of operation or mechanism of action for achieving the intended effect.
    b. A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.
    c. A list and description of each device for which clearance is requested.
    d. Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device.

510(k) RTA Checklist Element 15

15. Device is intended to be marketed with accessories and/or as part of a system.
    a. Submission includes a list of all accessories to be marketed with the subject.
    b. Submission includes a description (as detailed in item 14a., 14b., and 14d. above) of each accessory.
    c. A 510(k) number is provided for each accessory that received a prior 510(k) clearance

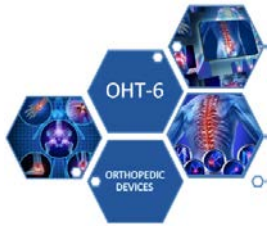
    AND

    A statement is provided that identifies accessories that have not received prior 510(k) clearance.

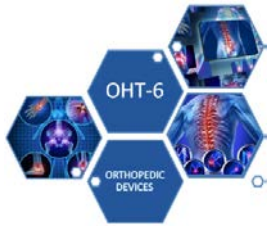


Device Description: Clear Yet Concise is Best

- Purpose of submission
- Written and illustrative descriptions (e.g., engineering drawings, cross-section images, exploded-view drawings, 3D PDFs) for all device components, especially for key technological features or mechanisms (e.g., interconnecting components, expanding feature, modular design, lattice structure)
- Specifications of device sizes, dimensions, and geometry
- Table of components
- Information is consistent with labeling documents and surgical technique guide is within the intended use of the device
- Description of unique device processing (e.g., additive manufacturing)
- Identification and description of all add-to-file changes since previous clearance



Indications for Use Statement



Intended Use vs. Indications for Use

Intended Use

Defined as the general purpose of the device or its function, and encompasses the indications for use.

Indications for Use

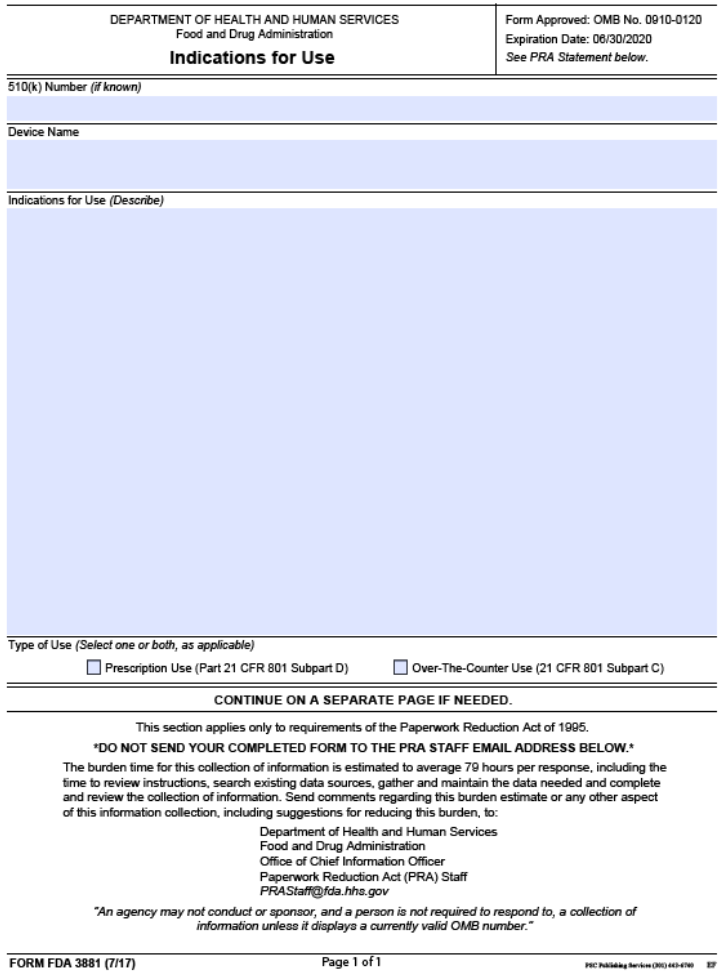
Defined in 21 CFR 814.20(b)(3)(i) as the disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended.

510(k) RTA Checklist Element 3

3. Submission contains an Indications for Use Statement with Rx and/or OTC designated

Recommended format:

Form FDA 3881



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Indications for Use *(Describe)*

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

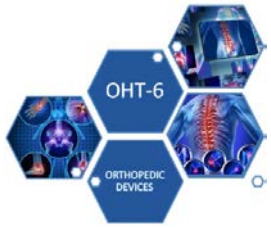
DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

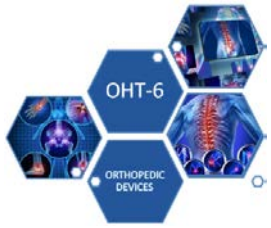
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (7/17) Page 1 of 1



510(k) RTA Checklist Element 18

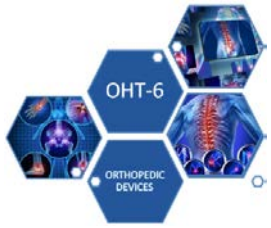
18. Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).
    a. Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).



Device-Specific Guidance: Spinal System 510(k)s

Indications for Use

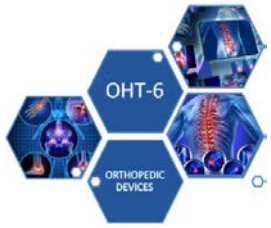
- State the indications for use at the beginning of your submission
- Avoid general and/or open-ended indications (e.g., instability, disc herniation, or general spinal curvature)



Indications within Device-Specific Classification Regulation

21 CFR 888.3070: Thoracolumbosacral pedicle screw systems

21 CFR 888.3075: Posterior cervical screw systems



Indications for Use Statement: Clear Yet Concise is Best

- Consistent throughout submission, including labeling and 510(k) Summary
- Avoid including extraneous information, such as information that is outlined in relevant labeling documents for the device, and reviewed for substantial equivalence as part of 510(k)
- Avoid ~~general or~~ open-ended indications
- Refer to Spinal System 510(k)s Guidance and/or device-specific classification regulation for indications for use if listed
- Refer to recent predicate clearances for example phrasing
- Provide purpose and justification for any difference in indications for use language compared to predicate device

Thank You!

FDA U.S. FOOD & DRUG ADMINISTRATION