

**DRAFT GUIDANCE DOCUMENT FOR THE PREPARATION OF
PREMARKET NOTIFICATION [510(K)] APPLICATIONS FOR
ORTHOPEDIC DEVICES**

The Basic Elements

Orthopedic Devices Branch
Division of General and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health
U.S. Food and Drug Administration

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INTRODUCTION

Purpose

The purpose of this document is to provide guidance to sponsors of 510(k) premarket notifications for orthopedic devices. The document is intended to identify the minimum set of information that should be provided to facilitate FDA's review of the 510(k) to determine substantial equivalence (SE).

The development of a guidance document for 510(k)s was initiated in response to concerns about time delays in the review of 510(k) documents, the inadequacy of the information submitted, and the repetitive nature of the deficiencies contained in submissions. This guidance is based on the Orthopedic Devices Branch's (ORDB's) recognition of certain criteria necessary to conduct an adequate evaluation of substantial equivalence for orthopedic devices. The purpose of this document is to suggest to the device manufacturer important administrative, descriptive, and scientific information that should be submitted in orthopedic device 510(k)s. Individual 510(k)s may require additional information not described in this document. Suggestions and recommendations reflect what ORDB has determined to be the minimum requirements for the evaluation of the device. While the use of this document to prepare a 510(k) will not ensure FDA clearance of a device, following the guidance will ensure that sufficient basic information is available to initiate a substantive review.

ORDB strongly recommends that a sponsor also obtain any available guidance or requirements specific to the subject device type. This device specific information would need to be submitted in addition to the general information described in this document.

Note that as scientific knowledge and regulations change, this guidance document will be periodically revised.

ADMINISTRATIVE INFORMATION

TRUTHFUL AND ACCURATE STATEMENT: A sample statement has been provided with this guidance document.

Please provide this statement at the beginning of the 510(k).

MANUFACTURER IDENTIFICATION:

- Provide the name and address of the manufacturer and sponsor of the 510(k) submission.
- Provide the manufacturer's establishment registration number.
- Identify the official contact person for all correspondence.

DEVICE IDENTIFICATION:

- Proprietary Name

- Common Name

- Classification Name and Reference

- Device Classification for the subject device and/or predicate device
Refer to Code of Federal Regulations, Title 21 (21 CFR). For example, the classification of "Orthopedic manual surgical instruments" is contained under 21 CFR 888.4540.

- Proposed Regulatory Class
Identify the proper regulatory class for the subject device, e.g., Class I, II, or III. 21 CFR 862-892 contains the regulatory classifications for medical devices. More specifically, 21 CFR 888 contains the regulatory classifications for orthopedic devices.

- Device Product Code
Identify the product code(s) for the device (e.g., the product code for a cerclage fixation system is JDQ). A device may have more than one product code (e.g., resorbable, screw-type bone anchors have the product codes of MAI and HWC). Product code listings may be obtained from the Division of Small Manufacturers Assistance (DSMA).

- Panel Code
The orthopedic devices panel code is 87. If the product is not classified under the orthopedic devices panel yet is reviewed by ORDB, then please identify the panel under which it is classified and provide the panel identification code (e.g., 79 is the product code for general surgical devices).

DEVICE BACKGROUND:

Specify whether the subject device component(s) or system:

1. has been previously cleared (i.e., determined to be substantially equivalent) by the FDA for different intended uses;
2. is currently being reviewed for different intended uses by the same or different branch(s) within ODE; and/or
3. has been previously submitted to the FDA for identical or different intended uses but was not determined to be substantially equivalent.

DEVICE INFORMATION

INTENDED USES/INDICATIONS:

Identify the specific intended use(s), including the specific diagnostic indications. If the 510(k) involves individual component(s) that are to be used as part of a complete system, please identify the system name. In addition, please state whether the device is cemented or cementless, if applicable.

DEVICE DESCRIPTION:

Provide complete engineering with all dimensions and tolerances of each component. These must identify all sizes and configurations.

Provide a written description of the components and how they interconnect.

Provide representative illustrations and/or clear photographs of the device that depict the intended uses. (For new or complicated designs, it may be appropriate to send a sample device.)

For implantable devices, describe the anatomical location and attachment mechanism for the device, and provide diagrams, illustrations, or photographs of the implant in situ.

If the 510(k) involves individual component(s) that are used as part of a complete system, then identify the system name and the 510(k) document number(s) through which the complete system was cleared.

If reference is made to information from a previous document, provide the document number, volume, page number, and submission date.

MATERIALS:

Identify the materials in each device component.

Identify the voluntary standards to which the device materials conform (e.g., Ti-4Al-6V conforms to ASTM F136).

Describe any additional processing that may affect material properties (e.g., ion bombardment, hot isostatic pressing, and coatings).

If the device has coupling of two or more components made of dissimilar metals, provide information that addresses the potential for galvanic corrosion.

TESTING INFORMATION:

When in-vitro, in-vivo, or mechanical testing information is necessary for the determination of substantial equivalence, the data should be submitted as a complete test report.

A complete test report consists of the following:

1. The name and address of facility performing the test.
2. The name of the study director, investigators, and supervisors involved in the study.
3. The dates that testing was initiated and completed and the date the final report was completed.
4. The objectives, methods, materials, deviations from referenced protocols and standards, results and conclusions of the test. These sections must include:
 - a. a description of the test system used and a schematic or clear photograph of the test setup;
 - b. a description of the samples tested including the differences, if any, in the composition, material structure and processing methods between the test samples and the device to be marketed (if multiple device sizes or configurations are under review, then select and justify the worst case device(s) to be tested);

- c. the assumptions of the test, including assumed physiological loading values and environmental conditions;
 - d. the load directions and magnitudes;
 - e. the full experimental data, complete to the extent that an independent conclusion and analysis can be made;
 - f. results (mean \pm standard error, standard deviation, etc., if applicable) from the testing of an adequate number of identical samples (e.g., 5) for each type of test and control specimens or statistical justification for the number of each;
 - g. statistical evaluation of the differences between the test results where appropriate;
 - h. the clinical implications of the results; and
 - i. a post-test failure analysis of the specimens for identification of cracks, plastic deformation and any other signs of failure, including the location of the point of failure initiation.
5. A bibliography of all references pertinent to the report.

The 510(k) information requirements for certain devices or design features may be covered by already established FDA or draft ORDB guidance documents. If applicable, submit the appropriate additional information according to the guidance document for that device or design feature. The guidances, which are available through DSMA, include, but are not limited to, the following topics:

tripartite biocompatibility
computer controlled medical devices;
calcium phosphate (Ca-P) coatings;
polyethylene;
spinal fixation systems;
cemented, semi-constrained knee prosthesis;
plasma sprayed porous coatings;
femoral stem prosthesis;
acetabular cup prosthesis
biodegradable polymer devices;
bone cement;
bone anchors;
modified metallic surfaces;
ceramic ball hip systems;
intramedullary rods; and
external fixation devices.

CLINICAL DATA:

When submitting clinical data in support of a 510(k) for significant risk devices, specify the FDA approved Investigational Device Exemptions (IDE) application under which the data were collected.

STERILIZATION INFORMATION:

Specify the sterilization status of the subject components as provided (e.g., sterile, nonsterile but sterilization is required prior to use, reusable, etc.). If the device may be resterilized, then additional information is necessary (see below).

The information described below was taken directly from "ORDB 510(k) Sterility Review Guidance" dated 7/3/97.

For **STERILE** devices:

1. Provide the sterilization method that will be used or was used [radiation, steam, EtO].
 - a. If the sterilization method is radiation, then provide the radiation dose that will be or was used.
 - b. If the sterilization method is EtO, then provide the maximum residual levels of ethylene oxide, ethylene chlorohydrin and ethylene glycol that will be or were met. These levels must be below those limits proposed in FR 27482 (6/23/78).
2. Provide the Sterility Assurance Level (SAL) you intend to meet or met.
3. Identify the sterility validation method that will be used or was used.
4. Provide a statement of whether device will be or is "pyrogen free" and a description of the method used to make that determination.
5. Provide a description of the packaging used to maintain sterility.
6. Provide sample labeling that reflects the "sterile" notation.

For **NONSTERILE** devices which must be sterilized prior to use or for devices which a sponsor states in the 510(k) that they may be **RESTERILIZED**:

1. Identify a recommended set or sets of sterilization process parameters (for steam - the cycle, temperature, and exposure time; for EtO - temperature, humidity, gas concentration, exposure time, and aeration cycle).
2. Provide the Sterility Assurance Level (SAL) you intend to meet or met ($\leq 10^{-6}$).
3. Identify the sterility validation method that will be used or was used (e.g., AAMI).
4. If the sterilization method is EtO, then identify the maximum residual levels of ethylene oxide, ethylene chlorohydrin and ethylene glycol that will be or were met. These levels must be below those limits proposed in FR 27482 (6/23/78).
5. If provided nonsterile, provide sample package labeling that reflects some type of nonsterile notation.
6. Provide a sample package insert that reflects the sterilization process parameters.

If the process parameters have not been validated, then state that the validation will be completed prior to marketing and that the package insert will be revised to reflect the validated parameters.

For **REUSABLE** devices:

1. Provide cleaning recommendations including any applicable disassembly instructions.
2. Provide sterilization information following the applicable guidance(s) above.
3. For the labeling:
 - a. Provide sample labeling with any recommended cleaning techniques and any applicable disassembly instructions.
 - b. If the sterilization process parameters have already been validated, then provide sample labeling that includes the recommended sterilization process parameters. Otherwise, if the parameters have not been validated, then provide a statement that, prior to marketing, the package insert will be revised to include the validated sterilization process parameters.

LABELING:

Provide draft package label(s) and package insert. Depending on the device type, surgical technique information may be requested.

Refer to the Sterilization section above for specific sterility information that is to be included in the labeling.

INDICATIONS ENCLOSURE:

A sample enclosure has been provided with this guidance document. The enclosure should include the subject 510(k) number (if known), subject device component or system name, and a complete statement of the intended uses/indications (as provided in the Intended Uses/Indications section above).

Please provide this enclosure at the beginning of the 510(k).

510(K) SUMMARY OR STATEMENT:

For all devices, provide either:

1. a summary (identified as "a 510(k) summary of safety and effectiveness") of any information respecting safety and effectiveness upon which a substantial equivalence determination is based;
or
2. a statement that such information respecting safety and effectiveness will be made available upon request by any person. A sample statement has been provided with this guidance document.

If you choose to provide a 510(k) summary instead of a statement, then the 510(k) summary should include the subject 510(k) number, subject device component or system name, complete statement of the intended uses/indications (as provided in the Intended Uses/Indications section above), brief device description, and a brief summary of the basis for substantial equivalence.

For all Class III devices, provide a summary of all adverse information. A sample Class III certification and summary form has been provided with this guidance document.

Please provide the 510(k) summary or statement (and, if applicable, the Class III summary) at the beginning of the 510(k).

SUBSTANTIAL EQUIVALENCE INFORMATION:

Identify a legally marketed predicate device to which the subject device is to be compared for the determination of substantial equivalence. Specify whether the predicate device is (1) a preamendments device (provide documentation to support preamendments status) or (2) a device previously cleared through 510(k) (identify the manufacturer, device name, and 510(k) number). Note that promotional material alone does not provide adequate evidence that the proposed predicate device is a preamendments or cleared device.

Provide a comparison (similarities and differences) of the predicate device(s) to the subject device in terms of design, materials, intended use, etc.