

**Class II Special Controls Guidance
Document: Knee Joint
Patellofemorotibial and Femorotibial
Metal/Polymer Porous-Coated
Uncemented Prostheses; Guidance for
Industry and FDA**

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

**Orthopedic Devices Branch
Division of General, Restorative, and Neurological Devices
Office of Device Evaluation**

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to Docket Number: 00N-0018 and the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact Mr. Peter G. Allen at (301) 594-2036 or by email pga@cdrh.fda.gov.

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Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

1. Introduction

This guidance document was developed as a special controls guidance to support the reclassification of (1) the knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis and (2) the knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis into class II (special controls). The patellofemorotibial prosthesis, or total knee, includes a metal femoral component, a tibial component consisting of a polyethylene tibial bearing fixed to a metal tibial baseplate, and a patellar component consisting of a polyethylene patellar bearing fixed to a metal baseplate. The femorotibial prosthesis, or uni-compartmental knee, includes a metal femoral component and a tibial component consisting of a polyethylene tibial bearing fixed to a metal tibial baseplate. One or all of the identified metal components may be porous-coated.

The devices, as classified, are intended for replacement of a knee joint or part of a knee joint, respectively. This guidance will be issued in conjunction with a Federal Register notice announcing the reclassification of these device types.

Following the effective date of this final reclassification rule any firm submitting a 510(k) premarket notification for (1) the knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis or (2) the knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

2. Background

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of the knee joint patellofemorotibial and femorotibial metal/polymer porous-coated uncemented prostheses. Thus, a manufacturer who intends to market a device of this generic type should (1) conform to the general controls of the Federal Food, Drug & Cosmetic Act (the Act), including the 510(k) requirements described in 21 CFR 807 Subpart E, (2) address the specific risks to health associated with the device

identified in this guidance and, (3) obtain a substantial equivalence determination from FDA prior to marketing the device. (See also 21 CFR 807.85).

This special control guidance document identifies the classification regulations and product codes for the knee joint patellofemoral and femoral metal/polymer porous-coated uncemented prostheses (Refer to Section 4 – **Scope**). In addition, other sections of this Class II Special Control Guidance Document list the risks to health identified by FDA and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with the knee joint patellofemoral and femoral metal/polymer porous-coated uncemented prostheses and lead to a timely 510(k) review and clearance. This document supplements other agency documents regarding the specific content requirements of a 510(k) submission. You should also refer to 21 CFR 807.87 and other agency documents on this topic, such as the **510(k) Manual - Premarket Notification: 510(k) - Regulatory Requirements for Medical Devices**, <http://www.fda.gov/cdrh/manual/510kprt1.html>.

Under “**The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**”¹, a manufacturer may submit a traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once a Class II Special Controls Guidance Document has been issued. Manufacturers considering modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the statutory and regulatory criteria in the manner suggested by the guidance and in your attempt to address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the “**A Suggested Approach to Resolving Least Burdensome Issues**” document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

3. The Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should

¹ <http://www.fda.gov/cdrh/ode/parad510.html>

describe how this special control guidance document was used during the device development and testing and should briefly describe the methods or tests used and a summary of the test data or description of the acceptance criteria applied to address the risks identified in this guidance document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of 807.87 as well as some other items that you should include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this Class II Special Controls Guidance Document.

Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Refer to Section 9 for specific information that should be included in the labeling for devices of the types covered by this guidance document.)

Summary report

We recommend the summary report contain:

- Description of the device and its intended use. The description should include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. (Refer to Section 5 for specific information that should be included in the device description for devices of the types covered by this guidance document.) You should also submit an "indications for use" enclosure.²
- Description of device design requirements.
- Identification of the Risk Analysis method(s) used to assess the risk profile in general as well as the specific device's design and the results of this analysis. (Refer to Section 6 for the risks to health generally associated with the use of this device that FDA has identified.)
- Discussion of the device characteristics that address the risks identified in this Class II Special Controls Guidance Document, as well as any additional risks identified in your risk analysis.
- A brief description of the test method(s) you have used or intend to use to address each performance aspect identified in Sections 7-8 of this Class II Special Controls Guidance Document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you should either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the

² Refer to <http://www.fda.gov/cdrh/ode/indicate.html> for the recommended format.

acceptance criteria that you will apply to your test results.³ (See also 21 CFR 820.30, Subpart C - Design Controls for the Quality System Regulation.)

- If any part of the device design or testing relies on a recognized standard, (1) a statement that testing will be conducted and meet specified acceptance criteria before the product is marketed, or (2) a declaration of conformity to the standard.⁴ Please note that testing must be completed before submitting a declaration of conformity to a recognized standard. (21 USC 514(c)(2)(B)). For more information, refer to the FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA**, <http://www.fda.gov/cdrh/ode/guidance/1131.html>.

If it is not clear how you have addressed the risks identified by FDA, or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), you can submit a traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering modifications to their own cleared devices should consider submitting Special 510(k)s.

The general discussion above applies to any device subject to a special controls guidance document. The following is a specific discussion of how you should apply this Class II Special Controls Guidance Document to a premarket notification for the knee joint patellofemoral tibial and femoral tibial metal/polymer porous-coated uncemented prostheses.

³ If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria, and thus differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

⁴ See Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(K)] Submissions), <http://www.fda.gov/cdrh/ode/reqrecstand.html>.

4. Scope

The scope of this document is limited to the following two device types:

Device Type	Regulation Number	Product Code
Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.	21 CFR §888.3565	MBH
Knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis.	21 CFR §888.3535	NJD

The classification identifications below identify the devices as they existed at the time of reclassification.

§888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.

- (a) *Identification.* A knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis is a device intended to be implanted to replace a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device is designed to achieve biological fixation to bone without the use of bone cement. This identification includes fixed-bearing knee prostheses where the ultra-high molecular weight polyethylene tibial bearing is rigidly secured to the metal tibial baseplate.
- (b) *Classification.* Class II (special controls). This special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA.”

§888.3535 Knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis.

- (a) *Identification.* A knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surface. It has no linkage across-the-joint. This generic type of device is designed to achieve biological fixation to bone without the use of bone cement. This identification includes fixed-bearing knee prostheses where the ultra-high molecular weight polyethylene tibial bearing is rigidly secured to the metal tibial baseplate.
- (b) *Classification.* Class II (special controls). This special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA.”

5. Device Description

You should identify your device, by regulation and product code, and include the following information:

- a description of the geometry of each component
- the dimensions for the total range of available sizes
- engineering drawings (femoral and tibial bearing component drawings should include the radii of curvature of the articulating surfaces in both the frontal and saggital planes)
- a description of any surface coating (e.g., porous coating)
- the minimum thickness of the ultra-high molecular weight polyethylene (UHMWPe) tibial bearing
- the minimum thickness of the UHMWPe patellar bearing
- the surface roughness of all surfaces, including any metal articulating surfaces (e.g., femoral condyles and tibial baseplate) and UHMWPe articulating surfaces (e.g., tibial and patellar bearings). [These data are usually described with a R_a value. Refer to ASTM F2083, ASTM F1672, and ISO 7207-2 for additional information.]
- a photograph of one size of each component
- information about the manufacturing processes, such as Hot Isostatic Pressing (HIP), heat treating, and crosslinking of UHMWPe
- the voluntary standards to which the materials used in each component of the device conform
- a list and brief description of any surgical instrumentation unique to the implantation of the knee prosthesis.

6. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the knee joint patellofemorotibial and femorotibial metal/polymer porous-coated uncemented prostheses addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as shown in the table below. You should also conduct a risk analysis, prior to submitting your 510(k), to identify any other risks specific to your device. The premarket notification should describe the risk analysis method. If you elect to use an alternative approach to address a particular risk identified in this guidance document, or have identified risks additional to those in the guidance, you should provide sufficient detail to support the approach you have used to address that risk.

Identified risk	Recommended mitigation measures
Adverse tissue reaction	Section 7
Infection	Section 8
Pain and/or loss of function	Sections 7 and 9
Revision	Sections 7 and 9

7. Preclinical Testing

FDA recommends that you provide the information below to evaluate the material and performance characteristics of your final, worst case, sterilized device.

A. Biocompatibility

These devices are permanent implants that have direct contact with bone. We recommend that you evaluate the biocompatibility of the materials in your device as described in the International Organization for Standardization (ISO) standard ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." You should select biocompatibility tests appropriate for the duration and level of contact with your device.

If *identical* materials are used in a similar predicate device, with the same type and duration of patient contact, you may identify the predicate device in lieu of performing the biocompatibility testing.

If you cannot identify a similar predicate device that utilizes the identical materials, and the materials in your device do not conform to one of the recognized consensus standards identified in Section 7, we recommend that you evaluate the biocompatibility of the materials in your device as described in ISO 10993-1.

B. Tibial Baseplate Component

For a total knee prosthesis, FDA recommends that you provide a complete report of fatigue testing of the porous-coated metal tibial baseplate (tray). FDA recommends the method described in ASTM F1800. FDA recommends testing five samples at various loads to develop an applied force/number of cycles (AF/N) curve with at least one sample surviving 10 million cycles; we also recommend that that you include a failure analysis. Alternatively, finite element analysis (FEA) or other calculations with validation of the model and assumed values may be appropriate.

For a unicompartmental knee prosthesis, no standardized test method currently exists for fatigue testing of the tibial baseplate component. Therefore, FDA recommends that you provide adequate information (e.g., engineering analysis, comparison of materials/geometry to predicate devices, mechanical testing) to demonstrate that your device is capable of withstanding the expected physiological loads to which it will be subjected.

C. UHMWPe Tibial Bearing Components

Wear, deformation, and cold-flow of UHMWPe are all closely related to the thickness of the UHMWPe component. Wear-through of thin tibial bearings has been reported extensively in the literature. Therefore, for both types of prostheses, FDA recommends that the minimum thickness of UHMWPe under the condyles of the thinnest sized bearing be at least 6mm. If the minimum thickness of your tibial bearing is below 6mm, FDA recommends that you provide a complete test report that demonstrates the ability of the UHMWPe to survive 10 million cycles of physiological loading in a functional knee simulator. The load set-up should include both sliding and rolling motions. FDA recommends using the methods

described in ASTM F1715 or ISO 14243-1, and ASTM F 2025 or ISO 14243-2, as a guide for UHMWPe wear testing and wear assessment, respectively.

Fatigue strength is also related to UHMWPe thickness for an all-UHMWPe tibial component of a total knee prosthesis. Cold flow of the UHMWPe has been shown to progress linearly with increasing load for all-UHMWPe tibial components thinner than 9mm. FDA recommends that you measure the overall thickness under the condyles, allowing for dovetails or other small cutout regions on the inferior surface that will not significantly reduce the fatigue strength. For any component with an overall thickness below 9mm, you should provide a complete report of fatigue testing. FDA recommends testing five samples at various loads to develop an AF/N curve with at least one sample surviving 10 million cycles; we also recommend that that you include a failure analysis. Alternatively, FEA or other calculations with validation of the model and assumed values may be appropriate.

D. Posterior-Stabilized Tibial Bearing Component

For a total knee prosthesis that is posterior-stabilized, FDA recommends that you provide a complete report of shear fatigue testing of the UHMWPe tibial post. FDA recommends testing five samples at various loads to develop an AF/N curve with at least one sample surviving 10 million cycles; we also recommend that that you include a failure analysis. Alternatively, FEA or other calculations with validation of the model and assumed values may be appropriate.

E. UHMWPe Material Property Characterization

For both types of prostheses, FDA recommends that you characterize the material properties of the final sterilized UHMWPe components according to the FDA guidance, **Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPe) Used in Orthopedic Devices**, dated March 28, 1995. This guidance is available at <http://www.fda.gov/cdrh/ode/180.pdf>.

F. Range of Motion and Constraint

For both types of prostheses, FDA recommends that you provide range of motion data on the tibiofemoral interface. You should include data on all modes of rotation (flexion/extension, internal/external, varus/valgus) and translation (medial/lateral, proximal/distal, anterior/posterior). We recommend that you include a discussion of the type of motion during articulation (e.g., sliding, rolling) and paths of articulation for all components (e.g., flexion rotation, anterior translation).

For both types of prostheses, FDA recommends that you provide constraint (or stability) data on the tibiofemoral interface. You should measure constraint using a worst case analysis of the anterior, posterior, medial, lateral and rotational tibiofemoral shearing forces during physiological loading. Using this approach, translational constraint is represented by the load required to induce subluxation, and rotational constraint is represented by the load required to induce a given angular rotation (e.g., $\pm 12^\circ$). For posterior-stabilized total knee designs, subluxation data are not necessary. However, you should provide the flexion angle of the initial contact between the femoral component and the tibial post and the posterior translation during flexion (femoral “rollback”).

For a total knee prosthesis, FDA recommends that you provide additional constraint data involving the lateral stability of the patellofemoral joint. You should provide lateral stability data at varying degrees of flexion to evaluate the device's resistance to patellar subluxation or dislocation. Patellofemoral implants should undergo increasing lateral shear loading under a constant physiological compressive force until component dislocation.

G. Contact Area/Stress

The mechanical environment of the articulating surfaces has a significant effect on the devices long-term survival. Minimizing the contact stress between articulating components reduces damage to the articulating surfaces.

For both types of prostheses, FDA recommends that you provide a complete report of the contact surface area between the femoral and tibial components at several different positions of flexion (e.g., 0°, 15°, 30°, 60°, 90°).

For a total knee prosthesis, FDA recommends that you also provide a complete report of the contact surface area between the femoral and patellar components at several different positions of flexion (e.g., 0°, 15°, 30°, 60°, 90°).

For both tests above, the report should include a contact stress analysis of the UHMWPe tibial and patellar bearing components at these flexion angles. You should estimate surface contact areas and contact stresses experimentally or by analytical methods validated experimentally.

H. Component Interlock Strength

Components that are snapped together or have some other type of interlocking mechanism (e.g., tibial bearing/baseplate, metal-backed patella, Morse taper) should be able to survive physiological loads.

To characterize the strength of attachment between the tibial bearing and tibial baseplate for both types of prostheses, FDA recommends that you provide a complete report of:

- static anterior and posterior shear testing
- static medial and lateral shear testing
- static tensile pull-off testing.

For a metal-backed patella component of a total knee prosthesis, FDA recommends that you provide a complete test report of:

- static tensile pull-off testing
- shear fatigue testing.

Static tensile pull-off testing determines the tensile force required to separate the UHMWPe bearing from the metal backing.

Shear fatigue testing of metal-backed patellar components determines the expected lifetime of the device. Refer to ASTM F1672 for information on relevant failure modes and test methods. FDA recommends testing five samples at various loads to develop an AF/N curve with at least one sample surviving 10 million cycles. Alternatively, FEA or other calculations with validation of the model and assumed values may be appropriate. A failure analysis should be included.

I. Porous Coatings

For both types of prostheses, FDA recommends that the porous coating have a volume porosity between 30 to 70 percent, an average pore size between 100 to 1,000 microns, interconnecting porosity, and a porous coating thickness of 500 to 1,500 microns.

If the porous coating on your device was cleared in one of your own previous 510(k)s, then no further characterization of the porous coating is needed. However, you should identify the other device and provide the 510(k) number for which clearance was received.

If the porous coating on your device was not cleared in one of your own previous 510(k)s, FDA recommends that you characterize the porous coating according to the FDA guidance, **“Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement**, dated April 28, 1994. This guidance is available at <http://www.fda.gov/cdrh/ode/827.pdf>.

J. Titanium Articular Surface Coatings

In the literature, titanium alloy (Ti-6Al-4V) articulating surfaces have been shown to produce metallic particles resulting in an adverse tissue response and high third-body wear. Therefore, for both types of prostheses, FDA recommends that the titanium femoral components have a treated surface (e.g., nitrogen ion). In addition, for both types of prostheses, FDA recommends that you provide a complete test report of the wear properties of the treated titanium alloy/UHMWPE articulating couple. The results should be compared to a cobalt-chrome alloy (CoCrMo)/UHMWPE articulating couple. Refer to ASTM F1715 or ISO 14243-1, and ASTM F 2025 or ISO 14243-2, for methods of wear testing and wear assessment, respectively.

We recommend that you use the applicable FDA guidance documents and consensus standards listed below to establish the material and performance characteristics of your device.

FDA Guidance Documents:

- “Draft Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Orthopedic Devices - The Basic Elements”
- “Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-Constrained Total Knee Prostheses”
- “Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement”
- “Guidance Document for Testing Non-articulating, ‘Mechanically Locked’ Modular Implant Components”

- “Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices”

ASTM International Voluntary Consensus Standards:

- F 67, “Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)”
- F 75, “Standard Specification for Cobalt - 28 Chromium - 6 Molybdenum Casting Alloy and Cast Products for Surgical Implants (UNS R30075)”
- F 86, “Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants”
- F 136, “Standard Specification for Wrought Titanium - 6 Aluminum - 4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications”
- F 620, “Standard Specification for Alpha Plus Beta Titanium Alloy Forgings for Surgical Implants”
- F 648, “Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants”
- F 732, “Standard Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses”
- F 746, “Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials”
- F 799, “Standard Specification for Cobalt – 28 Chromium – 6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)”
- F 983, “Standard Practice for Permanent Marking of Orthopedic Implant Components”
- F 1044, “Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings”
- F 1108, “Standard Specification for Titanium - 6 Aluminum - 4 Vanadium Alloy Castings for Surgical Implants (UNS R56406)”
- F 1147, “Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings”
- F 1160, “Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings”
- F 1223, “Standard Test Method for Determination of Total Knee Replacement Constraint”
- F 1377, “Standard Specification for Cobalt - 28 Chromium – 6 Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)”
- F 1472, “Standard Specification for Wrought Titanium – 6 Aluminum – 4 Vanadium Alloy (UNS R56400) for Surgical Implant Applications”
- F 1537, “Standard Specification for Wrought Cobalt – 28 Chromium – 6 Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, UNS R31539)”
- F 1580, “Standard Specification for Titanium and Titanium - 6% Aluminum - 4% Vanadium Alloy Powders for Coatings of Surgical Implants”
- F 1672, “Standard Specification for Resurfacing Patellar Prosthesis”
- F 1715, “Standard Guide for Wear Assessment of Prosthetic Knee Designs in Simulator Devices”
- F 1800, “Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements”
- F 1814, “Standard Guide for Evaluating Modular Hip and Knee Joint Components”

- F 1854, “Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants”
- F 1978, “Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber™ Abraser”
- F 2025, “Standard Practice for Gravimetric Measurement of Polymeric Components for Wear Assessment”
- F 2083, “Standard Specification for Total Knee Prosthesis”

International Organization for Standardization (ISO) Consensus Standards:

- ISO 5832-2, “Implants for surgery - Metallic Materials - Part 2: Unalloyed Titanium”
- ISO 5832-3, “Implants for surgery - Metallic Materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy”
- ISO 5832-4, “Implants for surgery - Metallic Materials - Part 4: Cobalt-chromium-molybdenum casting alloy”
- ISO 5832-12, “Implants for surgery - Metallic Materials - Part 12: Wrought cobalt-chromium-molybdenum alloy”
- ISO 5834-2, “Implants for surgery – Ultra-High-Molecular-Weight Polyethylene – Part 2: Moulded Forms”
- ISO 7207-1, “Implants for surgery – Femoral and tibial components for partial and total knee-joint prostheses – Part 1: Classification, definitions, and designation of dimensions”
- ISO 7207-2, “Implants for surgery – Components for partial and total knee-joint prostheses – Part 2: Articulating surfaces made of metal, ceramic and plastics materials”
- ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”
- ISO 14243-1, “Implants for surgery – Wear of total knee-joint prostheses – Part 1: Loading and displacement parameters for wear-testing with load control and corresponding environmental conditions for test”
- ISO 14243-2, “Implants for surgery – Wear of total knee-joint prostheses – Part 2: Methods of measurement”
- ISO 14879-1, “Implants for surgery – Total knee-joint prostheses – Part 1: Determination of endurance properties of knee tibial trays”

8. Sterility

FDA recommends that you provide sterilization information in accordance with the **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA**, <http://www.fda.gov/cdrh/ode/guidance/361.html>. The device should be sterile with a sterility assurance level (SAL) of 1×10^{-6} .

9. Labeling

The 510(k) should include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR 807.87(e).⁵

Directions for Use

As a prescription device, the porous-coated uncemented knee prosthesis is exempt from needing adequate directions for lay use. Nevertheless, under 21 CFR 807.87(e), we expect to see clear and concise instructions that delineate the technological features of the specific device and how the device is to be used in patients. Instructions should familiarize users who are trained in orthopedic surgery with the features of the device and how to use it in a safe and effective manner.

Intended Use/ Indications for Use for Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis

We recommend that you describe your intended use and indications. See the example below:

Intended to replace a knee joint in order to relieve pain and restore knee function, for indications such as osteoarthritis; inflammatory arthritis; traumatic arthritis; varus, valgus, or flexion deformities; and revision surgery.

Intended Use/ Indications for Use for Knee Joint Femorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis

We recommend that you describe your intended use and indications. See the example below:

Intended to replace part of a knee joint in order to relieve pain and restore knee function, for indications such as uni-compartmental osteoarthritis; inflammatory arthritis; traumatic arthritis; varus, valgus, or flexion deformities; and revision surgery.

⁵ Although final labeling is not required for 510(k) clearance, final labeling must also comply with the requirements of 21 CFR 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of part 801.