Guidance for Industry and FDA Staff

Non-clinical Information for Femoral Stem Prostheses

Document issued on: September 17, 2007

For questions regarding this document, contact Mr. John Goode (john.goode@fda.hhs.gov) or Ms. Elizabeth Frank (elizabeth.frank@fda.hhs.gov) at 240-276-3676.



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

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

GRZAN

Preface

Public Comment

Written 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. Alternatively, electronic comments may be submitted to http://www.fda.gov/dockets/ecomments. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/ode/guidance/1647.pdf. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number (**1647**) to identify the guidance you are requesting.

Table of Contents

I. INTRODUCTION 1

The Least Burdensome Approach *..... 2*

II. SCOPE 2

III. DEVICE DESCRIPTION 3

IV. STERILITY 4

V. BIOCOMPATIBILITY 4

VI. FATIGUE PROPERTIES 4

A. STEM FATIGUE TEST METHODS 5
B. FEMORAL NECK FATIGUE TEST METHODS 6
C. FATIGUE TEST METHODS FOR NOVEL STEM MATERIALS AND DESIGNS 7
D. FINITE ELEMENT ANALYSIS 8
E. FATIGUE TEST RESULTS 8

VII. MODULAR CONNECTIONS, FRETTING AND CORROSION TESTING 8

VIII. CLINICAL DATA 9

IX. TEST REPORTING 9

A. TEST FACILITY INFORMATION 9
B. TEST OBJECTIVES 9
C. MATERIALS AND METHODS 9
D. PROTOCOL DEVIATIONS 10
E. TEST PARAMETERS AND ACCEPTANCE CRITERIA 10
F. EXPERIMENTAL DATA 10
G. TEST RESULTS 10
H. DATA ANALYSIS 10
I. CONCLUSIONS 10
J. BIBLIOGRAPHY 10

X. LABELING 11

APPENDIX A. APPLICABLE REGULATIONS AND PRODUCT CODES 12

Guidance for Industry and FDA Staff

Non-clinical Information for Femoral Stem Prostheses

This guidance represents the Food and Drug Administration's (FDA'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 FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

FDA has developed this guidance document for members of industry who submit and FDA staff who review non-clinical tests and labeling of femoral stem prostheses. The terms "you" and "your" in this document refer to members of industry, also known as sponsors, submitters, or applicants. The terms "we," "us," and "our" refer to FDA. You should use this guidance to assist you in determining the appropriate non-clinical information and non-clinical testing to submit in premarket notifications (510(k)s), premarket approval **(**PMA) applications, and investigational device exemptions (IDEs) that include a femoral stem prosthesis.

This guidance document is not intended to describe all elements required in 510(k)s, IDEs, or PMAs. This guidance document supplements other FDA publications on 510(k), IDE, and PMA submissions and is not a replacement for these documents. In addition to the guidance and other resources listed below, there may be other guidance documents specific to your type of device located on the FDA website, http://www.fda.gov/cdrh/guidance.html.

Premarket Notification - 510(k) Information

For general information on 510(k)s, refer to 21 CFR 807.87 and "How to Prepare a 510(k) Submission" in CDRH's Device Advice at http://www.fda.gov/cdrh/devadvice/314.html. The guidance document "**Guidance for Industry and FDA Staff; Format for Traditional and Abbreviated 510(k)s**" at http://www.fda.gov/cdrh/ode/guidance/1567.pdf provides guidance on how to format an original submission for a Traditional or Abbreviated Premarket Notification Submission (510(k)).

Investigational Device Exemption (IDE) Information

For general IDE information, refer to 21 CFR Part 812 or to IDE Device Advice available at http://www.fda.gov/cdrh/devadvice/ide/index.shtml.

Premarket Approval Application (PMA) Information

For general PMA information, refer to 21 CFR 814 or http://www.fda.gov/cdrh/devadvice/pma/app_methods.html. In addition, there may be other guidance documents specific to your type of device located on the FDA website, http://www.fda.gov/cdrh/guidance.html.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe should 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 follow the guidance and 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.

II. Scope

This guidance addresses the development of non-clinical information, testing, and labeling of femoral stem prostheses. The recommendations in this document may be used for class II and class III femoral stem prostheses intended as components for cemented or uncemented (i.e., press-fit or for biological fixation) hemi or total hip replacement systems.[1] Femoral stems have a neck and shaft, which extends into the intramedullary canal, and may have either an integral femoral head or cone designed to accept modular heads. This document outlines the information we recommend you include for the femoral neck, shaft, and head (e.g., device description, sterility, biocompatibility, modular connection, head selection when determining femoral neck and stem strength). However, this guidance does not address the interaction of femoral heads and acetabular components (e.g., wear, range of motion, clearance, interfacial forces, constraint). If you have any questions on these topics, please contact the Orthopedic Joint Devices Branch.

[1] See table of regulations and product codes in Appendix A.

III. Device Description

FDA recommends that you identify your device by the applicable classification regulation and corresponding product code(s). See Attachment A of this guidance for a listing of regulations and product codes. In addition, we recommend that you provide the following information:

- name of the component, each of its parts, and part numbers
- description of the geometry of each component and function of each design feature
- dimensions for the entire range of available sizes
- representative photograph of each component
- engineering drawings
- surface roughness of all surfaces (R_a) (micrometers)
- material composition of each component
- information about the manufacturing processes that determine the material microstructure, and hence, its properties (e.g., heat treatments)
- characterization of coatings or surface modifications. For guidance, refer to "**Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement**"[2] at and/or the "**510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants**."[3]
- information about all modular connections, including how the parts are assembled and disassembled
- listing and brief description of any surgical instrumentation unique to the implantation of the femoral stem

If your stem geometry, materials, and/or sizes are identical to one of your previously legally marketed stems, we recommend that you identify the submission numbers, stems, materials, and/or sizes.

For engineering drawings, you should submit fully-dimensioned drawings for each size showing part numbers. Alternatively, you should supply representative drawings with a table of critical dimensions noted for each size. Engineering drawings for the stems should specifically illustrate the dimensions and tapers of the femoral neck; details of all modular connections, if applicable; and shape and dimensions of the femoral stem cross-section at the potting level. (See "Potting Level" discussion in Section VI.A.2.c.)

[2] http://www.fda.gov/cdrh/ode/827.html
[3] http://www.fda.gov/cdrh/ode/047.html

Regarding material composition of each component, you should include any voluntary standards to which the material conforms (any difference between the final product and the criteria in the referenced standard should be itemized and justified), trade names, establishments that process materials, reference numbers of any previous submission to FDA, or another relevant reference, that more fully characterizes the material (e.g., master file, 510(k), literature article).

IV. Sterility

FDA recommends that you provide sterilization information described in the guidance entitled, **Updated 510(k) Sterility Review Guidance K90-1**.[4] The device should be sterile with a sterility assurance level (SAL) of at least 1 x 10^{-6} using a sterilization cycle that has been validated in accordance with the Quality System regulation (21 CFR Part 820).

V. Biocompatibility

FDA recommends that you conduct biocompatibility testing as described in the guidance, **Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing**[5] for tissue/bone contacting, permanent implanted devices.

If the subject device has *identical* materials to a 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 predicate device that utilizes the identical materials, and the materials in your device do not conform to one of the FDA recognized consensus standards at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm, we recommend that you evaluate the biocompatibility of the materials in your device as described in ASTM F748 and/or ISO 10993-1.

VI. Fatigue Properties

FDA recommends that you provide the information below to evaluate the material and performance characteristics of your final, worst-case device(s). If sterilization affects the device performance, the tested device should be sterilized.

To demonstrate that the femoral stem will continue to function without failure in the intended patient population, you should perform a fatigue test on your worst-case femoral stem(s). In particular, we recommend using the test methods below to characterize the fatigue properties of the femoral stem. For each test method used, there may be a different worst-case stem. In addition, there may be femoral stem fatigue test methods (e.g., proximal stem fatigue testing), other than those outlined below, that mimic demonstrated clinical failure modes that your protocol should address.

[4] http://www.fda.gov/cdrh/ode/guidance/361.html.
[5] http://www.fda.gov/cdrh/g951.html.

If you believe fatigue testing is not necessary, you should provide a rationale in your submission. In addition to the bench testing identified in this guidance, FDA may recommend you perform a clinical evaluation of new or significantly different femoral stem materials or designs. If a clinical study is necessary, please see Section VIII: Clinical Data for additional information.

A. Stem Fatigue Test Methods

FDA recommends you perform stem testing as described below. For novel stem materials (e.g., polymer, polymer composite) and designs (e.g., resurfacing femoral stems), please refer to Section VI.C entitled, "Fatigue Test Methods for Novel Stem Materials and Designs." The performance standards associated with the fatigue test methods are outlined in Section VI.E.1.

1. Recommended Standards

We recommend the use of standards listed below or equivalent methods:

- ASTM F1612-95 (Reapproved 2005) Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components with Torsion.
- ASTM F1440-92 (Reapproved 2002) Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components without Torsion. FDA believes this standard is appropriate only for stems that are not susceptible to the additional effects of torsional loading (e.g., stems with round cross-sections).
- ISO 7206-4:2002 Implants for surgery-Partial and total hip joint prostheses- Part 4: Determination of endurance properties of stemmed femoral components. You should adjust the potting level described in this standard for stems less than 200mm to that described in the "Potting Level" Section VI.A.2.c.

2. Fatigue Testing Considerations

a. Worst-Case Design

We recommend that you test the stem dimensions and tolerances that produce the highest stressed components and greatest damage (i.e., worst-case). You should provide a rationale that explains how the following factors were considered in selecting your worst-case design: stem diameter, stem length, head and neck offset, modular connections, and material (i.e., substrate, modified surface).

b. Potting Medium

You should describe the potting medium composition. We recommend you use a bone cement or a material that is mechanically similar.

c. Potting Level

If you use the test method described in ISO 7206-4:2002, we recommend using a potting level at a minimum of 80 mm ± 2mm below the center of the head as measured vertically along the load application line from the center of the head to the potting level. Alternatively, if you follow ASTM F2068-03 and the test methods

described in ASTM F1612-95 (Reapproved 2000) or F1440-92 (Reapproved 2002), we recommend using a potting level with a minimum "unsupported implant length" of 50mm ± 2mm.

For very short stems that lack a sufficient potting medium to maintain fixation for the duration of the fatigue test, we recommend that the length of stem embedded in the potting medium should be, at most, one third of the total femoral stem length measured vertically from the center of the head to the distal tip.

If you choose to rely on ISO 7206-8:1995 as a performance criterion and as a basis for comparing the fatigue testing results of the subject device to the majority of legally marketed devices that have been tested using ISO 7206-4:1989, ASTM F1612-95 (Reapproved 2000) or F1440-92 (Reapproved 2002), we recommend you use a potting level as described above. For stems less than 200mm, therefore, the potting level FDA recommends differs from the protocol outlined in ISO 7206-4:2002.

You may need to adjust the potting level such that stress risers (e.g., stems with design features such as slots, ribs, changes in material, surface characteristics, or modular connections) that are near the potting level are above the potting level.

We recommend you report the stem shape and diameter at the potting level.

d. Lateral Head Deflection

We recommend that you measure the lateral head deflection under maximum load at the initiation of each test and include this information in your maximum bending moment calculation. FDA recommends you include exceeding a pre-defined deflection limit as a stem failure. Therefore, you should monitor lateral head deflection during the test and record deflections that exceed the deflection limit defined in your protocol.

B. Femoral Neck Fatigue Test Methods

FDA recommends you perform femoral neck fatigue testing as described below. The performance standards associated with this method are outlined in Section VI.E.2.

1. Recommended Standard

We recommend using the standard listed below or an equivalent method.

- ISO 7206-6:1992 Implants for surgery-Partial and total hip joint prostheses- Part 4: Determination of endurance properties of stemmed femoral components. You should follow the procedure outlined in clause 7.2.

2. Fatigue Testing Considerations

a. Worst-Case Design

We recommend that you test the femoral neck with dimensions and tolerances that produce the highest stressed components and greatest damage (i.e., worst-case). You should provide a rationale that explains how the following factors were considered in selecting your worst-case design: head and neck offset; modular connections; and material (i.e., substrate, modified surface).

b. Potting Medium

You should describe the potting medium composition and use a bone cement or a material that is mechanically similar.

C. Fatigue Test Methods for Novel Stem Materials and Designs

FDA may recommend that you conduct additional non-clinical or clinical testing when the *in vivo* loading profile of the new stem significantly differs from that of the stems for which the ASTM and ISO standards cited in this guidance were designed. FDA believes stems with new or significantly different stem materials or designs are likely to have significantly different loading profiles. Examples of these include polymer or polymer composites materials and resurfacing femoral stem designs. Any additional non-clinical testing of these materials and designs should address the following factors.

1. Polymer or Polymer Composite Stems

The standards in Section VI.A.1 include test procedures that assume proximal support for the stem has been lost leading to distal stem fatigue failure. These test procedures may not be appropriate for new polymer or polymer composite stem designs that fail at a load and/or number of cycles below what is described below (Section VI.E.1) due to new failure mechanisms. You may test these new stem designs by other testing methods, provided there is adequate clinical evidence, stress analyses, and mechanical bench testing that:

- justifies the load configurations and validates the test model; and
- demonstrates that the clinical failure mechanisms of the new stem (e.g., delamination, creep, shear failure, crazing, or chemical attack of polymer composite stems) would substantially deviate from failure mechanisms that would result if tested by ASTM F1612-95 (Reapproved 2000), F1440-92 (Reapproved 2002), or ISO 7206-4:2002 (i.e., fatigue crack in the distal shaft).

You should also provide a scientific rationale that the components and sizes you selected are representative of a worst-case scenario.

2. Resurfacing Femoral Stems

For resurfacing femoral stem prostheses, we recommend you complete cantilever fatigue testing for 5 million cycles. You should provide a complete test report containing fatigue strength testing of the representative worst-case stem of the femoral component under worst case physiological testing and loading conditions. You should include copies of all supporting literature references. In addition, you should explain why the component and methods you selected are representative of a worst-case scenario.

D. Finite Element Analysis

We believe finite element analysis (FEA) is primarily a development and design optimization tool, rather than a method by which physical performance of final devices can be demonstrated. For example, FEA may be used to identify the worst-case design for experimental testing. However, computer models may be appropriate to evaluate functional characteristics, if appropriate material properties and functional constraints are included and the computer models have been validated with experimental tests.

E. Fatigue Test Results

Your performance results for femoral stem and neck fatigue testing may be analyzed as follows.

1. Femoral Stem

When conducting the ISO/ASTM standard test methods, as described in Section VI.A.1, we recommend that you do the following:

- test six femoral stems and compare your results to the acceptance criteria given in either ISO 7206-8:1995 (cyclic loading with a minimum load of 300N and a maximum load of 2.3kN for five million cycles) or ASTM F2068-03 (clause 6.1.1).

- alternatively, the demonstrated fatigue strength of the stem should equal or exceed the demonstrated fatigue strength of a comparable legally marketed predicate femoral stem. We recommend that you test six devices for five million cycles. In addition, we recommend you provide a rationale that the components and methods you selected are representative of a worst-case scenario. You should consider using the potting levels as outlined above (Section VI.A.2.c).

2. Femoral Neck

When conducting the ISO standard test method, we recommend that you do the following:

- test six femoral stems and compare your results to the acceptance criteria in ASTM F2068-03 (clause 6.1.3).

- alternatively, demonstrated fatigue strength of the neck should equal or exceed the demonstrated fatigue strength of a comparable legally marketed predicate femoral neck. We also recommend that you test six devices for ten million cycles. In addition, we recommend you provide a rationale for the components and methods you selected are representative of a worst-case scenario.

VII. Modular Connections, Fretting and Corrosion Testing

In addition to addressing the fatigue properties of the stem, we recommend you perform modular connection, fretting, and corrosion testing To evaluate modular connections, fretting, and corrosion, refer to "**Guidance Document for Testing Non-Articulating, 'Mechanically**

Locked,' Modular Implant Components."[6] If you believe any of this testing is not necessary, you should provide a rationale in your submission.

VIII. Clinical Data

In addition to the bench testing identified in this guidance, it may be necessary to perform a clinical evaluation of new or significantly different femoral stem materials or designs to support a determination of substantial equivalence or a reasonable assurance of safety and effectiveness. The clinical study must be conducted under the Investigational Device Exemptions (IDE) regulation, 21 CFR Part 812, if performed in the U.S. For PMA devices, see also 21 CFR 814.15. FDA believes that the device addressed by this guidance document is a significant risk device as defined in 21 CFR § 812.3(m).[7] In addition to the requirement of having an FDA-approved IDE, sponsors of such trials must comply with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50). In addition, we recommend that you contact the Orthopedic Joint Devices Branch before you submit your IDE to discuss any questions you have related to the clinical study design.

IX. Test Reporting

We recommend that you present test data in a complete test report (or summary, if applicable) that includes the elements described below.

A. Test Facility Information

You should provide the name and address of the facility performing the test. You should also provide the names of the study director, investigators, and supervisors participating in the study. You should also provide the dates that testing was initiated and completed and the date the final report was completed.

B. Test Objectives

You should state the purpose of the test.

C. Materials and Methods

You should describe the samples tested, including the differences, if any, in the composition, material structure, and processing methods between the test samples and your device. If you submit multiple device sizes or configurations for review, you should test the worst-case device(s) and provide a rationale for the devices selected. You should also submit your test method or protocol. It should contain enough detail so an individual familiar with femoral stem fatigue testing can interpret the test results.

You should also describe the test system used and provide a schematic or clear photograph of the test setup. You should also provide all assumptions of the test, including assumed physiological loading values and environmental conditions. In addition, you should provide the load directions, magnitudes, potting level (see "Potting Level" discussion in Section VI.A.2.c),

[6] See http://www.fda.gov/cdrh/ode/916.html
[7] See http://www.fda.gov/oc/ohrt/irbs/devrisk.pdf.

and the stem shape and diameter at the potting level. You should also conduct a post-test failure analysis of the specimens that includes the following:

- an identification of cracks;
- an identification of plastic deformation; and
- an identification of any other signs of failure, including the location of the point of failure initiation.

D. Protocol Deviations

You should describe any protocol deviations and their effect on the ability of the test data to support your conclusions.

E. Test Parameters and Acceptance Criteria

You should report the test parameters and acceptance criteria that you use, including:

- an explanation of and rationale for critical test parameters;
- specifications or acceptance and rejection criteria; and
- a rationale that the specifications or acceptance and rejection criteria you selected are adequate for the clinical use of your device.

F. Experimental Data

We recommend that you submit all experimental data that includes enough information to support an independent analysis and conclusion.

G. Test Results

You should summarize your test results and include a statistical analysis where appropriate. The results should include a mean plus or minus standard error, or standard deviation. You should provide a statistical analysis of the differences between the test results, where appropriate.

H. Data Analysis

You should analyze the data, including any outlying points and anomalous results, and explain whether the data meet acceptance criteria.

I. Conclusions

We recommend that you describe the conclusions drawn from the test results and the clinical significance of the conclusions.

J. Bibliography

You should provide a bibliography and include copies of all cited references pertinent to the report.

X. Labeling

A 510(k) must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). A PMA must include all proposed labeling in accordance with 21 CFR 814.20(b)(10). The following suggestions will assist you in preparing labeling that fulfills the requirements of 21 CFR Part 801.[8]

Directions for use

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Nevertheless, we recommend providing clear and concise information that delineates the technological features of the specific device and how the device is used on patients. The instructions should encourage participation in local/institutional training programs designed to familiarize users with the features of the device and instructions on how to use the device in a safe and effective manner. Instructions should also describe the intended use, indications, and method of fixation.

Adequate instructions for use are essential, especially for small or short hip stems, so a physician can make an educated choice. Instructions should identify factors that may influence device performance, such as patient's age, activity level, weight, bone, and muscle quality. These instructions may be in the form of a precaution, warning, or a note to the surgeon in the labeling. Generally, contraindicated patient weight limits are not needed in the labeling for femoral hip stem systems.

In addition, the instructions for use should identify known adverse events. For example, stem loosening or fracture, particularly of smaller sized stems, is most likely to occur in patients who are young, physically active, have poor bone quality and/or are heavy.

[8] Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR 801 before introducing a medical device 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.

Appendix A. Applicable Regulations and Product Codes

Classification 21 CFR section	**Description**	**Product Code**	**Device Name**
888.3300	Hip joint metal constrained cemented or uncemented prosthesis.	KXD	prosthesis, hip, constrained, metal
888.3310	Hip joint metal/polymer constrained cemented or uncemented prosthesis.	KWZ	prosthesis, hip, constrained, cemented or uncemented, metal/polymer
888.3320	Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis	JDL	prosthesis, hip, semi-constrained (metal cemented acetabular component)
888.3330	Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis	KWA	prosthesis, hip, semi-constrained (metal uncemented acetabular component)
888.3340	Hip joint metal/composite semi-constrained cemented prosthesis.	KMC	prosthesis, hip, semi-constrained, composite/metal
888.3350	Hip joint metal/polymer semi-constrained cemented prosthesis.	JDI	prosthesis, hip, semi-constrained, metal/polymer, cemented
888.3353	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.	MAY	prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous cemented, osteophilic finish
		LZO	prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented
		MEH	prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate
888.3358	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.	LPH	prosthesis, hip, semi-constrained, metal/polymer, porous uncemented
		MBL	prosthesis, hip, semi-constrained, uncemented, metal/polymer, porous
888.3360	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.	JDG	prosthesis, hip, femoral component, cemented, metal
		KWL	prosthesis, hip, hemi-, femoral, metal
		LWJ	prosthesis, hip, semi-constrained, metal/polymer, uncemented
		JDD	prosthesis, upper femoral
888.3380	Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis.	JDH	prosthesis, hip, hemi-, trunnion-bearing, femoral, metal/polyacetal

Classification 21 CFR section	**Description**	**Product Code**	**Device Name**
888.3390	Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.	KWY	prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented
888.3400	Hip joint femoral (hemi-hip) metallic resurfacing prosthesis.	KXA	prosthesis, hip, femoral, resurfacing
888.3410	Hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis.	KXB	prosthesis, hip, pelvifemoral resurfacing, metal/polymer