

**Class II Special Controls Guidance
Document: Hip Joint Metal/Polymer
Constrained Cemented or Uncemented
Prosthesis; Draft Guidance for
Industry and FDA**

Draft Guidance – Not for Implementation

**This guidance document is being distributed for comment purposes only.
Draft released for comment on [release date as stated in FR Notice]**



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

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

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Preface

Public Comment

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, 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.

Additional Copies

Additional copies are available from the Internet at: [http://www.fda.gov/cdrh/\[specific address\]](http://www.fda.gov/cdrh/[specific address]), or CDRH Facts-On-Demand. In order to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1328 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis; Draft Guidance for Industry and FDA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.

Background

This guidance document was developed as a special control guidance to support the reclassification of the hip joint metal/polymer constrained cemented or uncemented prosthesis into class II. This guidance will be issued in conjunction with a Federal Register notice announcing the proposal to reclassify this device type. This guidance is issued for comment purposes only. If a final rule to reclassify this device type is not issued, this guidance document will not be issued as a special control.

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 hip joint metal/polymer constrained cemented or uncemented prosthesis. If the device is reclassified, a manufacturer who intends to market a device of this generic type must (1) conform with the general controls of the Food, Drug & Cosmetic Act, including the 510(k) requirements described in 21 CFR 807.81, (2) address the specific risks to health associated with the hip joint metal/polymer constrained cemented or uncemented prosthesis, and (3) receive a substantial equivalence determination from FDA prior to marketing the device.

This special control guidance document identifies the classification, product code, and classification definition for the generic hip joint metal/polymer constrained cemented or uncemented prosthesis. In addition, it identifies the risks to health and serves as the special control that, when followed and combined with the general controls, will generally address the risks associated with this generic device type and lead to a timely 510(k) review and clearance. For the specific content requirements of a 510(k) submission, preparers of submissions should refer to 21 CFR 807.87 and other agency documents on this topic.

Scope

FDA identifies the generic hip joint metal/polymer constrained cemented or uncemented prosthesis as an orthopedic device classified under 21 CFR 888.3310, product code KWZ. A hip joint metal/polymer constrained cemented or uncemented prosthesis is intended to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high-molecular-weight polyethylene with or without a metal shell made of alloys, such as cobalt-chromium-molybdenum and titanium alloys. This generic type of device is intended for use with or without bone cement (888.3027).

Risks to Health

FDA has identified the following four risks to health associated with the use of the hip joint metal/polymer constrained cemented or uncemented prosthesis:

1. infection
2. adverse tissue reaction
3. pain and/or loss of function
4. revision

The guidance documents, consensus standards, and labeling statements that follow will help manufacturers address the identified risks to health.

Controls

FDA believes that this special control will address the above identified risks to health associated with the use of the device. Manufacturers attempting to establish that their hip joint metal/polymer constrained cemented or uncemented prosthesis is substantially equivalent to a predicate hip joint metal/polymer constrained cemented or uncemented prosthesis device should demonstrate that their device complies with either the specific recommendations of this guidance or with an alternate means to establish equivalent safety and effectiveness of their device.

Manufacturers who reference recognized standards as part of their 510(k) submission should provide statements regarding conformance or “Declarations of Conformity” under the FDA Modernization Act of 1997. Because statements afford greater flexibility for device developers than “Declarations of Conformity,” submitters of 510(k)s should consider using guidance documents and consensus standards in this manner. For information regarding declarations of conformity, refer to FDA’s “Guidance on Recognition and Use of Consensus Standards,” which is available on our website at <http://www.fda.gov/cdrh/modact/k982.html>.

The FDA guidance documents, which present FDA’s current thinking, and consensus standards listed below will contribute to the design, manufacture, and clearance of safe and effective hip prosthesis. They also will help manufacturers address material concerns and performance testing

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methods for the device to reduce the identified risks associated with use of the device. The labeling statements listed below will provide information to practitioners that will contribute to safe and effective use of the device.

1. FDA Guidance Documents:

- a. "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Opposing Bone or Bone Cement"
- b. "Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components"
- c. "Draft Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Orthopedic Devices-The Basic Elements"
- d. "Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices"
- e. "510(k) Sterility Review Guidance K90-1" dated 02/12/1990
- f. "Draft Guidance Document for Femoral Stem Prostheses"
- g. "Draft Guidance Document for Testing Acetabular Cup Prostheses"

2. Consensus Standards:

- a. American Society for Testing and Materials (ASTM) Consensus Standards:
 - 1) F 67-95, "Standard Specifications for Unalloyed Titanium for Surgical Implant Applications"
 - 2) F 75-98, "Standard Specification for Cobalt-28 Chromium-6 Molybdenum Casting Alloy and Cast Products for Surgical Implants (UNS R 30075)"
 - 3) F 86-00, "Practice for Surface Preparation and Marking of Metallic Surgical Implants"
 - 4) F 90-97, "Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (UNS R30605)"
 - 5) F 136-98, "Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications"
 - 6) F 138-97, "Specification for Wrought 18 Chromium – 14 Nickel – 2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)"
 - 7) F 562-95, "Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy for Surgical Implant Applications"
 - 8) F 620-97, "Specification for Titanium-6 Aluminum-4 Vanadium ELI Alloy Forgings for Surgical Implants (UNS R56401)"
 - 9) F 648-98, "Standard Specification for Ultra-High Molecular Weight Polyethylene Powder and Fabricated Form for Surgical Implants"
 - 10) F 745-95, "Specification for 18 Chromium – 12.5 Nickel 2.5 Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications"
 - 11) F 746-87 (99), "Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials"
 - 12) F 799-96, "Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNSR311537)"
 - 13) F 983-86 (96), "Practice for Permanent Marking of Orthopedic Implant Components"

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- 14) F 1044-95, "Standard Test Method for Shear Testing of Porous Metal Coatings"
 - 15) F 1108-97a, "Specification for Titanium-6 Aluminum-4 Vanadium Alloy Casting for Surgical Implants (UNS R56406)"
 - 16) F 1147-99, "Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings"
 - 17) F 1160-98, "Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical Coatings"
 - 18) F 1377-98a, "Standard Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants UNS R30075"
 - 19) F 1440-92 (97), "Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components Without Torsion"
 - 20) F 1472-99, "Specification for Wrought Titanium – 6 Aluminum – 4 Vanadium Alloy for Surgical Implant Applications (UNS R56400)"
 - 21) F 1537-94, "Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants"
 - 22) F 1580-95, "Standard Specification for Titanium and Titanium-6% Aluminum-4% Vanadium Alloy Powders for Coatings of Surgical Implants"
 - 23) F 1612-95, "Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components with Torsion"
 - 24) F 1814-97a, "Standard Guide for Evaluating Modular Hip and Knee Joint Components"
 - 25) F 1820-97, "Standard Test Method for Determining the Axial Disassembly Force of a Modular Acetabular Device"
 - 26) F 1854-98, "Test Method for Stereological Evaluation of Porous Coatings on Medical Implants"
 - 27) F 1978-00, "Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber™ Abraser"
- b. International Organization for Standardization (ISO) Consensus Standards:
- 1) ISO 5832-1997, "Implants for Surgery - Metallic Materials - Part 1: Wrought Stainless Steel"
 - 2) ISO 5832-1996, "Implants for Surgery - Metallic Materials - Part 3: Wrought Titanium 6-Aluminium 4-Vanadium Alloy"
 - 3) ISO 5832-1996, "Implants for Surgery - Metallic Materials - Part 4: Cobalt-Chromium-Molybdenum Casting Alloy"
 - 4) ISO 5832-1992, "Implants for Surgery - Metallic Materials - Part 9: Wrought High Nitrogen Stainless Steel"
 - 5) ISO 7206-1989, "Implants for Surgery - Partial and Total Hip Joint Prostheses - Part 4: Determination of Endurance Properties of Stemmed Femoral Components with Application of Torsion"
 - 6) ISO 7206-1995, "Implants for Surgery Partial and Total Hip Joint Prostheses -Part 8: Endurance Performance of Stemmed Femoral Components with Application of Torsion"

3. Labeling

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a. Intended Use/ Indications for Use:

The hip joint metal/polymer constrained cemented or uncemented prosthesis is intended to replace a hip joint. The device is intended for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered.

b. Precautions:

- (1) When using metallic cups intended for biological fixation or cemented use only, surgeons should consider providing immediate resistance to tensile forces between the metallic cup and the acetabular bone through the use of bone screws, spikes, screw threads, fins, etc.
- (2) To correctly position the metallic locking ring, surgeons should consult the manufacturer's instructions for appropriate device assembly.
- (3) Physicians should consider component malposition, component placement, and the effect on range of motion when using modular heads (with sleeves or skirts) and extended liners.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.]

Medical Devices: Draft Guidance; Class II Special Controls
Guidance Document: Hip Joint Metal/Polymer Constrained
Cemented or Uncemented Prosthesis; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled, "Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis." This guidance document was developed as a special control guidance to support the reclassification of the hip joint metal/polymer constrained cemented or uncemented prosthesis into class II. This guidance is not final nor is it in effect at this time.

DATES: Submit written comments concerning this guidance by [Insert the date 90 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in the brackets in the heading of this document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the

SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled, "Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818.

FOR FURTHER INFORMATION CONTACT:

John S. Goode,
Center for Devices and Radiological Health (HFZ-410),
Food and Drug Administration,
9200 Corporate Blvd.,
Rockville, MD 20850,
(301) 594-2036

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document was developed as a special control guidance to support the reclassification of the hip joint metal/polymer constrained cemented or uncemented Prosthesis into class II. This guidance will be issued in conjunction with a FEDERAL REGISTER notice announcing the

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I left as is because
Joe OK'd + revised
JW.

proposal to reclassify this device type. This draft guidance may not be implemented until the reclassification process undergoes notice and comment and completes final rulemaking to reclassify this device. If a final rule to reclassify this device type is not issued, this guidance document will not be issued as a special control.

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 hip joint metal/polymer constrained cemented or uncemented prosthesis. If the device is reclassified, a manufacturer who intends to market a device of this generic type must (1) conform with the general controls of the Federal Food, Drug and Cosmetic Act (the act), including the premarket notification requirements described in FDA regulations (21 CFR 807.81), (2) address the specific risks to health associated with the hip joint metal/polymer constrained cemented or uncemented prosthesis, and (3) receive a substantial equivalence determination from FDA prior to marketing the device.

This special control guidance document identifies the classification, product code, and classification definition for the generic hip joint metal/polymer constrained cemented or uncemented prosthesis. In addition, it identifies the risks to health and serves as a special control that, when

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followed and combined with the general controls, will generally address the risks associated with this generic device type and lead to a timely 510(k) review and clearance.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking about the hip joint metal/polymer constrained cemented or uncemented prosthesis. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute and regulations.

The agency has adopted Good Guidance Practices (GGPs), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (65 FR 56468, September 19, 2000). This draft guidance document is issued as a Level 1 guidance in accordance with the GGP regulations.

III. ELECTRONIC ACCESS

In order to receive "Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the

document number (1328) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, FEDERAL REGISTER reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. Guidance documents are also available on the Dockets Management Branch Internet site at <http://www.fda.gov/ohrms/dockets/default.htm>.

VI. Comments

Interested persons may, on or before [Insert *date 90 days after date of publication in the FEDERAL REGISTER*], submit to Dockets Management Branch (address above) written comments regarding this draft guidance. Submit two copies of any comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance

document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

DATED: