

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0318]

DMB

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Certifier	<i>R. DeLeon</i>

Medical Devices; Draft Guidance; Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis." This draft guidance document was developed as a special control guidance to support the reclassification of the hip joint metal/polymer constrained cemented or uncemented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. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify this device type. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments concerning this guidance by [*insert date 90 days after date of publication in the Federal Register*].

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis" to the Division of Small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. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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>.

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This draft guidance document was developed as a special control guidance to support the reclassification of the hip joint metal/polymer constrained cemented or uncemented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. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule 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 draft 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 followed and combined with the general controls, will generally address the risks associated with this generic device type and lead to a timely section 510(k) of the act (21 U.S.C. 360(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 (21 CFR 10.115; 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>.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance on or before [*insert date 90 days after date of publication in the Federal Register*]. 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 draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 8/22/01
August 22, 2001.

Linda S. Kahan

Linda S. Kahan,
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Center for Devices and Radiological Health.

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Regina Sedes