

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

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Certifier D. Hawkins

[Docket No. 01D-0318]

Medical Devices; 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 guidance entitled "Class  
II Special Controls Guidance Document: Hip Joint  
Metal/Polymer Constrained Cemented or Uncemented  
Prosthesis." Elsewhere in this issue of the FEDERAL  
REGISTER, FDA is issuing a final rule to reclassify this  
type of device into class II.

DATES: Submit written or electronic comments on agency  
guidances at any time.

ADDRESSES: Submit written requests for single copies on a  
3.5" diskette of the guidance entitled "Class II Special  
Controls Guidance Document: Hip Joint Metal/Polymer  
Constrained Cemented or Uncemented Prosthesis" to the  
Division of Small Manufacturers, International, and  
Consumer Assistance (HFZ-220), Center for Devices and  
Radiological Health (CDRH), Food and Drug Administration,

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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. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

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

In the FEDERAL REGISTER of September 6, 2001 (66 FR 46641), FDA published a proposed rule to reclassify the hip joint metal/polymer constrained cemented or uncemented prosthesis from class III (premarket approval) to class II (special controls) based on new information regarding this

device contained in a reclassification petition submitted by the Orthopedic Surgical Manufacturers Association. FDA also identified the document "Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis" as the special control capable of providing reasonable assurance of safety and effectiveness for this device.

Interested persons were invited to comment on the draft guidance by December 5, 2001. FDA received three comments. Two comments commended FDA's proposal to reclassify these devices and agreed that the guidance proposed as the special control was adequate to provide reasonable assurance of the safety and effectiveness of the device. One comment stated that FDA's proposed special control was inadequate to protect against certain types of device failure, specifically shell-bone interface failure that may occur after implantation of this highly constrained device.

FDA agrees that shell-bone interface failure may occur after implantation of the device. FDA has revised the precaution section in the guidance document to clarify that it addresses device failure at the shell-bone interface.

## II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current thinking on special controls for 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 statutes and regulations.

## III. Electronic Access

In order to receive the guidance entitled "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 (1393) 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. Updated on a regular basis, the CDRH home page includes 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>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available at <http://www.fda.gov/ohrms/dockets>.

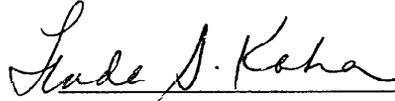
#### IV. Comments

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (see ADDRESSES). Two copies of any comments are to be submitted, 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

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: 4/15/02

April 15, 2002.



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

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