DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Thomas Craig
President
Orthopedic Surgical Manufacturers Association
1962 Deep Valley Cove
Germantown, TN 38138

Re: Reclassification Order:
Petition for Reclassification of Orthopedic Knee Prostheses
Docket Number: 00N-0018

Dear Mr. Craig:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition on behalf of the Orthopedic Surgical Manufacturers Association for reclassification of the knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis, which is intended to be implanted to replace a knee joint, and the knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis, which is intended to be implanted to replace part of a knee joint. FDA concludes that these devices and substantially equivalent devices of these generic types should be reclassified from class III into class II. This order, therefore, reclassifies these two knee joint prostheses, and substantially equivalent devices of these generic types into class II, under the generic names knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis and knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis, effective immediately. This order also identifies the special controls applicable to the devices as 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."

FDA identifies these generic types of devices, the subjects of this reclassification, as follows:

1. The 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.

2. The 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

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prostheses where the ultra high molecular weight polyethylene tibial bearing is rigidly secured to the metal tibial baseplate.

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking. A postamendments class III device remains in class III and requires premarket approval, unless and until:

1. FDA reclassifies the device into class I or II;

2. FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act (21 U.S.C. 360c(f)(2)), as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA); or

3. FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).

As you know, on October 16, 1997, FDA filed your petition requesting reclassification of the knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis and the knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis from class III into class II. The petition was submitted under section 513(f)(2) of the act, now section 513(f)(3) of the act, as amended by the FDAMA, and under 21 CFR 860.134 of the agency's regulations. In accordance with section 513(f)(1) of the act, the knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis and the knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis were automatically classified into class III because they were not within types of devices that were introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and they had not been found substantially equivalent to devices placed in commercial distribution after May 28, 1976 that were subsequently reclassified into class II or class I. In order to reclassify these devices intended to be implanted to replace a knee joint or part of a knee joint, into class II, it is necessary that the proposed device class have sufficient regulatory controls to provide reasonable assurance of safety and effectiveness of the devices for their intended use.

Pursuant to 21 CFR 860.125 and 860.134, FDA consulted with the Orthopedic and Rehabilitation Devices Panel (the Panel) at a meeting held on January 12 and 13, 1998. The Panel recommended unanimously that the knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis, which is intended to be implanted to replace a knee joint, and recommended (five to three) that the knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis, which is intended to be implanted to replace part of a knee joint, be reclassified from class

III into class II because the Panel believes that special controls will provide reasonable assurance of the safety and effectiveness of the devices. The Panel recommended that the special controls for these devices be FDA guidance documents, consensus standards, and postmarket surveillance. These recommendations were based on the information in the reclassification petition, the summary and analysis of the information in the petition, the information presented during the Panel meeting held on January 12 and 13, 1998, and the Panel members' personal knowledge of, and clinical experience with, the devices.

FDA tentatively agreed with the Panel's recommendation to reclassify the devices from class III into class II. FDA agreed with the Panel that FDA guidance documents and consensus standards be special controls for the devices. FDA disagreed with the Panel that postmarket surveillance is an appropriate special control for the devices. In their deliberations, the Panel stated that is was important that adverse device outcomes be reported to FDA and be followed through postmarket surveillance. FDA believes that another postmarket mechanism better addresses the Panel's concern. FDA believes that the existing Mandatory Device Reporting system is the appropriate mechanism to report and follow such adverse events. Therefore, FDA has determined that postmarket surveillance under section 522 is unnecessary to address this concern.

The recommendations of the Panel and FDA's tentative conclusions were published in the Federal Register of March 7, 2000 (65 FR 12015) (enclosed), and interested persons were invited to comment by June 7, 2000. FDA received three comments on the notice of panel recommendation that supported the Panel's recommendation to reclassify these devices into class II. FDA agrees with these comments.

One comment also requested the following three changes in the device identifications:

1. Change the proposed porous coating thickness range from 600 to 1500 microns to 500 to 1600 microns "to increase the potential for bone ingrowth."

2. Change the proposed volume porosity percentage range from 30 - 70% to 30 - 80% based upon a transcortical animal study model that demonstrated more bone formation occurred with the use of higher volume porosity materials than with the use of lower volume porosity materials.

3. Include in the device identifications a statement that a new coating material that meets the identification parameters (volume porosity, average pore size, interconnecting porosity, and porous coating thickness) and has equivalent performance (demonstrated by mechanical testing and/or animal studies) can be determined to be substantially equivalent to a legally currently marketed device without human clinical information.

Based on consideration of this comment and reevaluation of previously cleared orthopedic joint prostheses, FDA has revised the device identifications published in the notice of panel recommendation. FDA has determined that the words metal and polymer adequately define the material composition of the devices and that it is unnecessary to list in the device identifications all the

types of metals and polymers in legally marketed devices of these types. FDA has also removed the porous coating characteristics from the device identifications that were in the notice of panel recommendation because it is also unnecessary to list porous coating characteristics ranges in the device identifications. FDA has concluded that it is more appropriate to describe materials and porous coating characteristics in the class II special controls guidance document. FDA notes that guidance documents can be updated after devices with new materials are demonstrated to be substantially equivalent to legally marketed devices.

FDA agrees with the Panel's recommendation to reclassify the knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis and the knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis from class III into class II. This decision is based on the administrative record, which consists of the reclassification petition, the transcript and minutes of the January 12 and 13, 1998 Panel meeting, the Panel member's data sheets containing their recommendations, and all other information identified in this letter.

On January 16, 2003, FDA issued the guidance document entitled "Class II Special Controls Guidance: Knee Joint Patellofemorotibial and the Knee Joint Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA." It incorporates the four FDA guidance documents and eleven ASTM standards that FDA identified as special controls in the notice of panel recommendation. FDA notes that the class II special controls guidance document includes the updated ASTM consensus standards. FDA has also incorporated into the class II special controls guidance document one additional FDA guidance document, sixteen additional ASTM standards, and eleven International Organization for Standardization (ISO) consensus standards. This class II special controls guidance document is now the special control for these devices. A copy of the class II special controls guidance document is enclosed.

After review of the information submitted in the petition and consultation with the Panel regarding the reclassification petition, FDA has determined that the knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis, which is intended to be implanted to replace a knee joint, and the knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis, which is intended to be implanted to replace part of a knee joint, and as described and identified herein can be reclassified from class III into class II with the establishment of special controls. Based on the available information, FDA believes that class II with special controls will provide reasonable assurance of the safety and effectiveness of these devices.

FDA identified the following four risks to health associated with the use of the knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis and the knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis: infection, adverse tissue reaction, pain and/or loss of function, and revision. FDA notes that these risks to health are also associated with the use of the cemented versions of knee joint prostheses. FDA has determined that general controls and special controls can control these risks to health.

A notice announcing this reclassification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Drive, room 1-23, Rockville, MD 20857 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

If you have any questions concerning this reclassification order, please contact Mr. Peter G. Allen at 301-594-2036 extension 157. Thank you for your cooperation during the reclassification process. Please share this information with your membership.

Sincerely yours,

Philip J. Phillips
Deputy Director
Science & Regulatory Policy
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure