DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 00N–0018]

Medical Devices; 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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has reclassified two fixed-bearing knee joint prostheses, 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 has reclassified the devices from class III (premarket approval) into class II (special controls). The special control that will apply is a 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.'' The agency is reclassifying these devices into class II because special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the devices, and there is sufficient information to establish

special controls. The agency is also announcing that it has issued an order in the form of a letter to the Orthopedic Surgical Manufacturers Association (OSMA) reclassifying the devices.

EFFECTIVE DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Peter G. Allen, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

SUPPLEMENTARY INFORMATION:

I. Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq*.), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA

advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f)) of the act (21 U.S.C. 360c(f)) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act (21 U.S.C. 360c(f)(2)); or (3) FDA issues an order finding the device to be substantially equivalent, under 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 offered devices by means of premarket notification (510(k)) procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of postamendments devices is governed by section 513(f)(3) of the act (21 U.S.C.360c(f)(3)). This section states that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or that a manufacturer or importer of a device may petition

the Secretary of Health and Human Services (the Secretary) for the issuance of an order classifying the device into class I or class II. FDA's regulations in 21 CFR 860.134 set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Under section 513(f)(3)(B)(i) of the act, the Secretary may, for good cause shown, refer a petition to a device panel. If a petition is referred to a panel, the panel shall make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain: (1) A summary of the reasons for the recommendation, (2) a summary of the data upon which the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed.

II. Recommendations of the Panel

On July 25, 1997, FDA filed a reclassification petition submitted by OSMA, requesting 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, from class III into class II. FDA consulted with the Orthopedic and Rehabilitation Devices Panel (the Panel) regarding the reclassification petition. During a public meeting on January 12 and 13, 1998, the Panel recommended that FDA reclassify these two devices from class III into class II. The Panel recommended that the special controls

for these devices be FDA guidance documents, consensus standards, and postmarket surveillance.

FDA considered the Panel's recommendation and tentatively agreed that these generic types of devices should be reclassified from class III to class II. FDA agreed with the Panel that guidance documents, which include the consensus standards, are appropriate special controls for the devices.

FDA disagreed with the Panel that postmarket surveillance, under section 522 of the act (21 U.S.C. 3601), is an appropriate special control for these devices. In their deliberations, the Panel stated that it was important that adverse device outcomes be reported to FDA and be followed through postmarket surveillance. However, FDA believes that another postmarket mechanism better addresses the Panel's concern. FDA believes that the existing mandatory Medical Device Reporting system is the appropriate mechanism to report and follow such adverse events. Therefore, FDA determined that postmarket surveillance under section 522 of the act is unnecessary to address the Panel's concerns and to reasonably assure the safety and effectiveness of the devices.

Subsequently, in the **Federal Register** of March 7, 2000 (65 FR 12015), FDA issued the Panel's recommendation for public comment. FDA received three comments on the notice of panel's recommendation that supported the Panel's recommendation to reclassify the devices into class II. FDA agrees with these comments.

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

(1) Change the proposed porous coating thickness range from 600 to 1,500 microns to 500 to 1,600 microns ''to increase the potential for bone ingrowth.''

(2) Change the proposed volume porosity percentage range from 30 to 70 percent to 30 to 80 percent 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.

FDA agrees that the lower limit of the porous-coating thickness should be 500 microns not 600 microns. The lower limit of the Panel's recommendation was 500 microns, but due to a typographical error a lower limit of 600 microns was printed in the notice of panel recommendation. FDA is noting and correcting this error. FDA disagrees with the request to raise the upper limit of the porous coating thickness range to 1,600 microns because the comment did not provide any data to support this requested change. FDA notes that a higher porous coating thickness is not necessarily excluded and that a sponsor of a new device may submit material characterization information to demonstrate that a device with a thicker porous coating material is substantially equivalent to a legally marketed predicate device.

FDA disagrees with the comment that suggested a change in the volume porosity percentage range in the identifications because the agency does not believe that a single animal study is sufficient to demonstrate in vivo performance of joint replacement devices in humans. FDA also notes that a

material with a higher porosity is not necessarily excluded and that a sponsor of a new device may submit material characterization information to demonstrate that a more porous material is substantially equivalent to a legally marketed predicate device.

FDA disagrees with the comment that suggested that the identifications should allow for a change to a new material that is comparable, because this addition to the identifications is unnecessary. The device identifications do not exclude the use of new materials in devices whose safety and effectiveness performance can be demonstrated to be substantially equivalent to legally marketed devices.

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 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 applicants demonstrate that devices with new materials are substantially equivalent legally marketed devices.

III. FDA's Conclusion

After reviewing the data in the petition and presented at the Panel meeting, and after considering the Panel's recommendation and the comments on the notice of panel recommendation, 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, can be reclassified from class III into class II.

On February 3, 2003, FDA issued an order to the petitioner reclassifying the devices into class II (special controls). The order also identified the special control applicable to these devices as a 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.'' The class II special controls guidance document incorporates the 4 FDA guidance documents and the 11 American Society for Testing Materials (ASTM) consensus standards that were identified as proposed special controls for the devices 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, 16 additional ASTM consensus standards, and 11 International Organization for Standardization (ISO) consensus standards. This class II special controls guidance document is now the special control for these devices.

An alternative approach to the special controls guidance document may be used if such approach satisfies the applicable statute and regulations. Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for one of these devices will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

Accordingly, as required by 21 CFR 860.134(b)(6) and (b)(7) of the regulations, FDA is announcing the reclassification of the generic 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, from class III into class II. In addition, FDA is issuing this final rule to codify the reclassification of the device by adding new §§ 888.3565 and 888.3535.

IV. Electronic Access

In order to receive the 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’’ 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 the document. Enter the document number 1418 followed by the pound sign (#). Follow the remaining prompts to complete your request.

Persons interested in obtaining a copy of the FDA guidance document may do so using the Internet. The Center for Devices and Radiological Health

(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. You may access the CDRH home page at http://www.fda.gov/cdrh. You may search for all CDRH guidance documents at http://www.gfa.gov/cdrh/guidance.html. Guidance documents are also available at http://www/fda.gov/ohrms/dockets.

V. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this reclassification is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the

regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of these devices from class III to class II will relieve all manufacturers of the devices of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to these devices, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency, therefore, certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of $110 million or more on either the private sector or state, local, and tribal governments in the aggregate, and, therefore, a summary statement or analysis pursuant to section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VII. Federalism

FDA has analyzed this final rule in accordance with Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that this final rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VIII. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no new collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (Public Law. 104–13) is not required.

List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

1. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 888.1 is amended by adding paragraph (e) to read as follows:

§ 888.1 Scope

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(e) Guidance documents referenced in this part are available on the Internet at http://www.fda.gov/cdrh/guidance.html.

3. Section 888.3535 is added to subpart D to read as follows:

§ 888.3535 Knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis.

(a) *Identification*. A 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 prostheses where the ultra-high molecular weight polyethylene tibial bearing is rigidly secured to the metal tibial baseplate.

(b) *Classification*. Class II (special controls). The special control is FDA's guidance: ''Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA.'' See § 888.1 for the availability of this guidance.

4. Section 888.3565 is added to subpart D to read as follows:

§ 888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.

(a) *Identification*. A 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 base plate.

(b) *Classification*. Class II (special controls). The special control is FDA's guidance: ''Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated

Uncemented Prostheses; Guidance for Industry and FDA.'' See § 888.1 for the availability of this guidance.

Dated: March 10, 2003.

Linda S. Kahan,

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[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

BILLING CODE 4160–01–S