

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has reclassified two fixed-bearing knee joint prostheses, the knee joint patellofemoral 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 Patellofemoral 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 DATE: This rule is effective March 24, 2003.

FOR FURTHER INFORMATION CONTACT:

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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 patellofemoral 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