

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 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, 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 Patellofemoral 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 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. 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 Patellofemoral and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA" via your fax machine, call the CDRH Facts-