

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 99P-1864]

Orthopedic Devices: Reclassification of the Hip Joint
Metal/Polymer Constrained Cemented or Uncemented Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying the hip joint metal/polymer constrained cemented or uncemented prosthesis intended to replace a hip joint from class III (premarket approval) to class II (special controls). FDA is also identifying the guidance document entitled "Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis" as the special control that the agency believes will reasonably ensure the safety and effectiveness of the device. This reclassification is being undertaken based on new information regarding the device contained in a reclassification petition submitted by the Orthopedic Surgical Manufacturers Association (OSMA), under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 Amendments), the Safe Medical Devices Act of 1990 (SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDA is also

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revising the device identification to accurately describe the device.

DATES: This regulation is effective [insert date 30 days after date of publication in the FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In the FEDERAL REGISTER of September 6, 2001 (66 FR 46563), FDA published a proposed rule to reclassify the hip joint metal/polymer constrained cemented or uncemented prosthesis from class III to class II based on new information respecting the device. FDA identified the guidance document entitled "Class II Special Controls Guidance: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis" as the special control capable of providing reasonable assurance of safety and effectiveness for the device.

Interested persons were given until December 5, 2001, to comment on the proposed rule. 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. The comment stated that this risk to health could only be addressed through a clinical testing requirement in a premarket approval application. The comment stated that the proposed rule was legally and procedurally flawed because FDA failed to address this specific risk to health in the proposed rule.

FDA disagrees with the comment. FDA agrees that shell-bone interface failure may occur after implantation of the device. FDA notes that the Orthopedic and Rehabilitation Devices Panel (the Panel) discussed this specific risk to health at the Panel meeting held on November 4, 1999, that was cited in the September 6, 2001, proposed rule to reclassify the device. Their recommendation to reclassify the device from class III into class II was made in full awareness of this risk to health because the Panel believed that this risk to health could be controlled through implementation of special controls. Although clinical trials were discussed at the meeting, the Panel did not

recommend that clinical trials be a special control to reasonably assure the safety and effectiveness of this device. The agency concurred with the Panel's recommendation. The "Risks to Health" section of the proposed rule included a discussion of possible revision and of pain and/or loss of function due to a variety of causes, including device failure. The agency believes that discussion of device failure, as well as discussion of device failure in the draft guidance, logically included device failures that were the result of problems with the shell-bone interface. Although FDA did not specifically state that the first bulleted precaution statement in the draft guidance document was intended to address the risk of this specific device failure, the agency believes that the scope of the precaution statement in the draft guidance document did cover this risk. In order to provide additional clarity, FDA has revised this precaution statement in the final guidance document. Because the agency believes its proposed rule and draft guidance raised the concerns associated with this risk and because the final guidance includes further clarification, FDA does not agree that the proposed rule was legally or procedurally flawed.

II. FDA's Conclusion

Based on a review of the available information referenced in the preamble to the proposed rule and placed on file in FDA's

Dockets Management Branch, FDA concludes that the special controls, in conjunction with general controls, provide reasonable assurance of the safety and effectiveness of this device. The agency is also revising the device identification to accurately describe the currently marketed device. Elsewhere in this issue of the FEDERAL REGISTER, FDA is announcing the availability of the guidance document.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action 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.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612) (as amended by subtitle D of the Small Business Regulatory Fairness Enforcement Act of 1996 (Public Law 104-121)), 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 this device from class III will relieve all manufacturers of these devices of the cost of complying with the premarket approval requirements in section 515 of the act (21 U.S.C. 360e). Moreover, compliance with special controls for these devices will not impose significant new costs on affected manufacturers because most of these devices already comply with the special controls. 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 \$100 million or more on either the private sector or

State, local, or tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in 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 the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VI. Paperwork Reduction Act of 1995

FDA concludes that this final rule does not contain information collection provisions that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

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, it is proposed that 21 CFR part 888 be 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 888.3310 is revised to read as follows:

§ 888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis.

(a) Identification. A hip joint metal/polymer constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high-molecular-weight polyethylene with or without a metal shell, made of alloys, such as cobalt-chromium-molybdenum and titanium alloys. This generic type of device is intended for use with or without bone cement (§ 888.3027).

(b) Classification. Class II (special controls). The special control for this device is the FDA guidance document

entitled "Class II Special Controls Guidance: Hip Joint
Metal/Polymer Constrained Cemented or Uncemented Prosthesis."

Dated: 4/15/02.
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Linda S. Kahan,
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