

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

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[Docket No. 2003N-0561]

**Orthopedic Devices; Effective Date of Requirement for Premarket Approval
for Hip Joint Metal/Polymer or Ceramic/Polymer Semiconstrained
Resurfacing Cemented Prosthesis**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis. The agency also is summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices. This action implements certain statutory requirements.

DATES: This rule is effective *[insert date of publication in the Federal Register]*. Under this final rule, a PMA or a notice of completion of a PDP is required to be filed on or before *[insert date 90 days after date of publication in the Federal Register]*, for any hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis.

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

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295) and the Safe Medical Devices Act of 1990 (Public Law 101-629), 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).

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) established the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA or a notice of completion of a PDP until 90 days after FDA issues a final rule requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the act, whichever is later. Also, a preamendments device subject to the rulemaking procedure under section 515(b) of the act is not required to have an approved investigational device exemption (IDE) (see part 812 (21 CFR part 812)) contemporaneous with its interstate distribution until the date identified by FDA in the final rule

requiring the submission of a PMA for the device. At that time, an IDE is required only if a PMA has not been submitted or a PDP completed.

When a rule to require premarket approval for a preamendments device is finalized, section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)) requires that a PMA or notice of completion of a PDP for any such device be filed within 90 days of the date of issuance of the final rule or 30 months after the final classification of the device under section 513 of the act, whichever is later. If a PMA or notice of completion of a PDP is not filed by the latter of the two dates, commercial distribution of the device must cease.

The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or notice of completion of a PDP is not filed by the latter of the two dates, and no IDE is in effect, the device is deemed to be adulterated within the meaning of section 510(f)(1)(A) of the act (21 U.S.C. 360(f)(1)(A)), and subject to seizure and condemnation under section 304 of the act (21 U.S.C. 334), if its distribution continues. Shipment of devices in interstate commerce will be subject to injunction under section 302 of the act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the act (21 U.S.C. 333). In the past, FDA has requested that manufacturers take action to prevent the further use of devices for which no PMA has been filed and may determine that such a request is appropriate for the class III device that is the subject of this regulation.

The act does not permit an extension of the 90-day period after issuance of a final rule within which an application or notice is required to be filed. The House Report on the 1976 amendments states that “* * * the thirty month ‘grace period’ afforded after classification of a device into class III * * * is

sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application of premarket approval” (H. Rept. 94–853, 94th Cong., 2d sess. 42 (1976)).

In the **Federal Register** of September 4, 1987 (47 FR 33686), FDA issued a final rule classifying the hip joint metal/polymer semiconstrained resurfacing cemented prosthesis into class III. Subsequently, FDA determined that the ceramic/polymer semiconstrained resurfacing cemented prosthesis was substantially equivalent to the metal/polymer semiconstrained resurfacing cemented prosthesis.

In the **Federal Register** of March 5, 2004 (69 FR 10390), FDA issued a proposed rule to require the filing of a PMA or a notice of completion of a PDP for the hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis (the proposed rule). In accordance with section 515(b)(2)(A) of the act, FDA included in the preamble to the proposed rule the agency’s proposed findings regarding the degree of risk of illness or injury intended to be eliminated or reduced by requiring the device to meet the statute’s approval requirements as well as the benefits to the public from the use of the device.

The March 5, 2004, proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the agency’s proposed findings. In accordance with section 515(b)(2)(A) of the act, FDA also provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Interested persons requesting a change in the classification of the devices were to submit a petition by March 22, 2004. The comment period closed June 3, 2004.

FDA received no petitions requesting a change in the classification of the hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis. FDA received no comments on the proposed rule.

II. Device Subject to This Proposal

A hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis is a two-part device intended to be implanted to replace the articulating surfaces of the hip while preserving the femoral head and neck. 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 includes prostheses that consist of a femoral cap component made of a metal alloy, such as cobalt-chromium-molybdenum, or a ceramic material, that is placed over a surgically prepared femoral head, and an acetabular resurfacing polymer component. Both components are intended for use with bone cement.

III. Findings With Respect to Risks and Benefits

Under section 515(b)(3) of the act, FDA is adopting the findings as published in the proposed rule of March 5, 2004. As required by section 515(b) of the act, FDA published its findings regarding the following topics: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring that these devices have an approved PMA or a declared completed PDP and (2) the benefits to the public from the use of the device.

These findings are based on the reports and recommendations of the Orthopaedic Device Classification Panel, an FDA advisory committee, for the classification of the device, along with FDA's comprehensive review of the literature.

IV. The Final Rule

Under section 515(b)(3) of the act, FDA adopts the findings as published in the preamble to the proposed rule and issues this final rule to require premarket approval for the hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis. This final rule revises part 888 (21 CFR part 888).

Under the final rule, a PMA or a notice of completion of a PDP is required to be filed on or before 90 days after the date of publication of this rule in the **Federal Register** (see **DATES**), for any hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis that was in commercial distribution before May 28, 1976, or that has been found by FDA to be substantially equivalent to such a device on or before 90 days after the date of publication of this rule in the **Federal Register**. If a PMA or notice of completion of a PDP is filed for any such device within this time limit, the applicant will be permitted to continue marketing its hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis during FDA's review of its submission. Any other hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis that was not in commercial distribution before May 28, 1976, is required to have an approved PMA or a declared completed PDP in effect before it may be marketed.

If a PMA or a notice of completion of a PDP for a hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis is not filed on or before 90 days after the date of publication of this rule in the **Federal Register**, that device is deemed adulterated under section 501(f)(1)(A) of the act (21 U.S.C. 351(f)(1)(A)), and commercial distribution of the device

must cease immediately. The device may, however, be distributed for investigational use, if the requirements of the IDE regulations (part 812) are met. Because the hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis is intended to be used as an implant, FDA considers it to be a significant risk device as defined in the IDE regulation in § 812.3(m)(1).

The exemptions in § 812.2(c)(1) and (c)(2) from the requirements of the IDE regulations for preamendments class III devices cease to apply to any hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis that is either: (1) Not legally on the market on or before 90 days after the date of publication of this rule in the **Federal Register** or (2) legally on the market but for which a PMA or notice of completion of a PDP is not filed within 90 days after the date of publication of this final rule in the **Federal Register**, or for which PMA approval has been denied or withdrawn. FDA cautions that manufacturers who are not immediately planning to submit a PMA or notice of completion of a PDP should submit IDE applications to FDA by 60 days after the date of publication of this final rule in the **Federal Register**, to minimize the possibility of interrupting shipment of the device. At this time, FDA is not aware of any firm that is marketing this device.

V. PMA Requirements

A PMA for these devices must include the information required by section 515(c)(1) of the act. Such a PMA should also include a detailed discussion of the risks identified previously, as well as a discussion of the effectiveness of the device for which premarket approval is sought. In addition, a PMA must include all data and information on the following topics: (1) Any risks known, or that should be reasonably known, to the applicant that have not been

identified in this document; (2) the effectiveness of the device that is the subject of the application; and (3) full reports of all preclinical and clinical information from investigations on the safety and effectiveness of the device for which premarket approval is sought.

VI. PDP Requirements

A PDP for any of these devices may be submitted in lieu of a PMA, and must follow the procedures outlined in section 515(f) of the act. A PDP should provide the following information: (1) A description of the device, (2) preclinical trial information (if any), (3) clinical trial information (if any), (4) a description of the manufacturing and processing of the devices, (5) labeling of the device, and (6) all other relevant information about the device. In addition, the PDP must include progress reports and records of the trials conducted under the protocol on the safety and effectiveness of the device for which the completed PDP is sought.

Information about the PDP process is also available from the Center for Devices and Radiological Health on the Internet at http://www.fda.gov/cdrh/devadvice/pma/app_methods.html#product_dev.

VII. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

VIII. 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), 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 not a significant regulatory action 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. Because the device has fallen out of use and FDA is not aware of any firm marketing the device, the agency has concluded that there is little or no interest in marketing this device in the future. The agency, therefore, certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$110 million. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA). The burden hours required for § 888.3410(c), included in the collection entitled “Premarket Approval of Medical Devices—21 CFR Part 814,” are reported and approved under OMB control number 0910–0231. Therefore, clearance by OMB under the PRA 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 888.3410 is revised to read as follows:

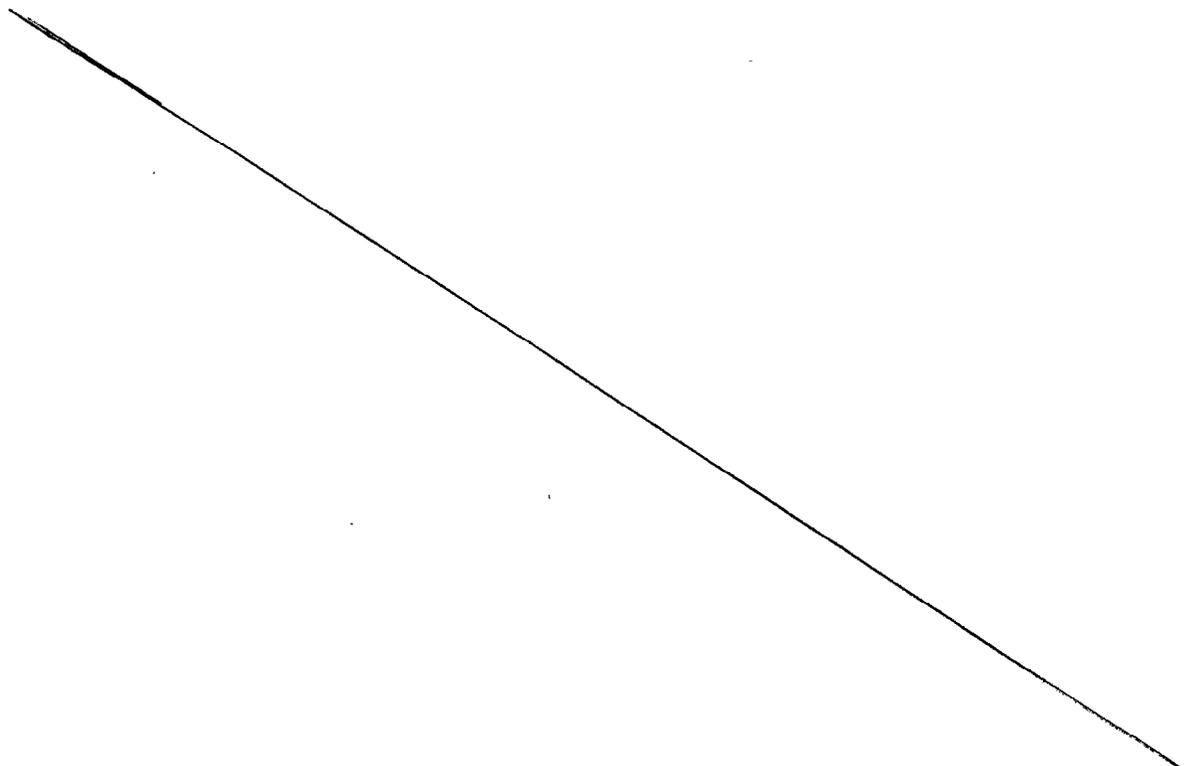
§ 888.3410 Hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis.

(a) *Identification.* A hip joint metal/polymer or ceramic/polymer semi-constrained resurfacing cemented prosthesis is a two-part device intended to be implanted to replace the articulating surfaces of the hip while preserving the femoral head and neck. 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 includes prostheses that consist

of a femoral cap component made of a metal alloy, such as cobalt-chromium-molybdenum, or a ceramic material, that is placed over a surgically prepared femoral head, and an acetabular resurfacing polymer component. Both components are intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before [*insert date 90 days after date of publication in the Federal Register*], for any hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before [*insert date 90 days after date of publication in the Federal Register*], been found to be substantially equivalent to a hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis that was in commercial distribution before May 28, 1976. Any other hip joint metal/



polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis must have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: SEP 23 2004
September 23, 2004.

Linda S. Kahan

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

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