

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 870 and 886

DMB

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[Docket No. 99N-0035]

**Medical Devices; Reclassification of Six Cardiovascular Preamendments Class III
Devices into Class II**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying six cardiovascular preamendments devices from class III (premarket approval) into class II (special controls). FDA is also identifying the special controls that the agency believes will reasonably ensure the safety and effectiveness of the devices. This reclassification is being undertaken on the agency's own initiative based on new information under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Safe Medical Devices Act of 1990 and the Food and Drug Administration Modernization Act of 1997. The agency is also revising the identification of one of the devices subject to this rule to simplify the classification regulation and is correcting a typographical error that was incorporated into the regulations.

DATES: This rule is effective *[insert date 30 days after date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Bette L. Lemperle, Center for Devices and Radiological Health (HFZ-453), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8262.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 15, 1999 (64 FR 12774), FDA published a proposed rule to reclassify 38 preamendments class III devices into class II and to establish special controls for these devices (the March 1999 proposal). FDA invited interested persons to comment on the proposed rule by June 14, 1999. FDA received one request to reopen the comment period for six cardiovascular devices. The request noted that FDA had not made the guidance documents that were proposed as special controls for these six devices available for comment through FDA's good guidance practices (GGP's). The requestor asked that FDA extend the comment period until at least 90 days after the guidance documents were publicly available. In the **Federal Register** of April 19, 2000 (65 FR 20995), FDA announced the availability of six guidance documents for these devices and reopened the comment period on the reclassification of the six devices (65 FR 20933) until July 18, 2000.

FDA received two comments on the vascular graft prosthesis of less than 6 millimeters diameter (§ 870.3450 (21 CFR 870.3450)). These comments are summarized and addressed in section II of this document. FDA received no comments on the other five devices. In this final rule, FDA is reclassifying the six devices into class II with guidance documents as special controls.

The devices that are being reclassified in this final rule are:

- Vascular graft prosthesis of less than 6 millimeters diameter (§ 870.3450) (combined with vascular graft prosthesis of 6 millimeters and greater diameter (§ 870.3460 (21 CFR 870.3460)) and renamed vascular graft prosthesis)
- Pacemaker lead adaptor (21 CFR 870.3620)
- Annuloplasty ring (21 CFR 870.3800)
- Cardiopulmonary bypass defoamer (21 CFR 870.4230)
- Cardiopulmonary bypass arterial blood line filter (21 CFR 870.4260)
- Cardiopulmonary bypass oxygenator (21 CFR 870.4350)

In the **Federal Register** of March 31, 2000 (65 FR 17138), FDA published a final rule to reclassify 28 other preamendments class III devices that were included in the March 1999 proposal. That final rule included an error in the classification of aqueous shunts (21 CFR 886.3920). The word "neurovascular" was incorrectly used for the word "neovascular." FDA is correcting that error in this final rule.

II. Comments

FDA received two comments addressing the vascular graft prosthesis of less than 6 millimeters diameter (§ 870.3450). Both comments supported the reclassification of the device.

(Comment 1) One comment recommended that vascular graft prostheses constructed of materials of animal origin, and instruments, tools, and devices used to create vascular graft prostheses should be included in the identification of the vascular graft prosthesis of less than 6 millimeters diameter. The comment stated that the change would reflect technological advances made in the medical device industry since the device was classified in 1980.

FDA disagrees with this comment. The identification for the vascular graft prosthesis of less than 6 millimeters in diameter excludes grafts made of materials of animal origin, including human umbilical cords. FDA notes that the biological vascular graft was designated as a transitional device and that it was regulated as a drug before the vascular graft prosthesis of less than 6 millimeters in diameter, a device made of synthetic material, was classified in 1980. FDA also notes that the identification of the vascular graft of less than 6 millimeters in diameter does not include instruments, tools, and other devices used to create vascular prostheses.

(Comment 2) This comment raised the following five issues:

1. The comment recommended combining the classification regulations of the class III vascular graft prosthesis of less than 6 millimeters diameter (§ 870.3450) and the class II vascular graft prosthesis of 6 millimeters and greater diameter (§ 870.3460) because separate regulations would no longer be necessary if the vascular graft prosthesis of less than 6 millimeters is reclassified into class II.

FDA agrees that it is appropriate to combine the classification regulations of the vascular graft prosthesis of less than 6 millimeters diameter and the vascular graft prosthesis of 6 millimeters and greater diameter into a single device classification. FDA notes that the special control guidance document for the vascular graft prosthesis of less than 6 millimeters diameter also applies to the vascular graft prosthesis of 6 millimeters and greater diameter.

2. The comment proposed that the reclassification apply to indications for use other than those explicitly excluded in the device identification.

FDA disagrees. The revised device identification accurately identifies the indications for use of the vascular graft prosthesis addressed by the special control guidance document.

3. The comment included minor editorial changes to the guidance document that clarify its meaning.

FDA agrees with the editorial changes.

4. The comment proposed to revise the guidance document to reflect the revised identification for the vascular graft.

FDA agrees that the scope of the guidance document should be consistent with the revised identification for the device and has revised the guidance document accordingly.

5. The comment recommended that vascular grafts of animal origin, and instruments, tools, and devices used to create vascular graft prostheses, should not be reclassified into class II.

As noted above, FDA is not reclassifying vascular grafts of animal origin in this final rule. The device identification does not include instruments, tools, and other devices used to create vascular graft prostheses; FDA is not reclassifying the devices used by physicians to create vascular grafts.

III. FDA's Conclusion

FDA has concluded, based on a review of the available information, that the special controls identified below provide reasonable assurance of the safety and effectiveness of these six devices.

The numbers in parentheses are the Facts-on-Demand (FOD) numbers to access copies of the guidances identified as the special controls. FOD instructions follow the list of guidances.

- Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions (11/1/00) (FOD #372)
- Guidance Document for Vascular Prostheses 510(k) Submissions (11/1/00) (FOD #1357)
- Guidance for Annuloplasty Rings 510(k) Submissions (1/31/00) (FOD #1358)
- Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions (11/29/00) (FOD #1632)
- Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions (11/29/00) (FOD #1622)
- Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions (11/13/00) (FOD #1361)

To receive these guidance documents via your fax machine, call the Center for Devices and Radiological Health (CDRH) FOD system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system and enter the FOD number listed above followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of these guidance documents also may do so by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes these guidance documents, device safety alerts, **Federal Register** notices, and 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 issues. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. These guidance documents are also available at <http://www.fda.gov/cdrh/ODE>.

The proposed rule identified FDA's biocompatibility and sterility guidances as special controls for these six devices. Upon review, we have decided not to codify these guidances as special

controls for these devices. Instead, we are now referencing the sterility and biocompatibility guidances within each of the device specific guidances. FDA had incorrectly listed the titles of these guidances and is correcting the references within the device specific guidances to read, “Use of International Standard ISO–10993 ‘Biological Evaluation of Medical Devices Part I: Evaluation and Testing’ ” (FOD #164) and “510(k) Sterility Review Guidance (2/12/1990) (#K90–1)” (FOD #361).

IV. Environmental Impact

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

V. 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 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 these devices 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 proposed 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 proposed rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VI. 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 order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects

21 CFR Part 870

Medical devices.

21 CFR Part 886

Medical devices, Ophthalmic goods and services.

PART 870—CARDIOVASCULAR DEVICES

1. The authority citation for 21 CFR part 870 continues to read as follows:

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

2. Section 870.3450 is revised to read as follows:

§ 870.3450 Vascular graft prosthesis.

(a) *Identification.* A vascular graft prosthesis is an implanted device intended to repair, replace, or bypass sections of native or artificial vessels, excluding coronary or cerebral vasculature, and to provide vascular access. It is commonly constructed of materials such as polyethylene terephthalate and polytetrafluoroethylene, and it may be coated with a biological coating, such as albumin or collagen, or a synthetic coating, such as silicone. The graft structure itself is not made of materials of animal origin, including human umbilical cords.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled “Guidance Document for Vascular Prostheses 510(k) Submissions.”

§ 870.3460 [Removed]

3. Section 870.3460 *Vascular graft prosthesis of 6 millimeters and greater diameter* is removed.

4. Section 870.3620 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 870.3620 Pacemaker lead adaptor.

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(b) *Classification*. Class II (special controls). The special control for this device is the FDA guidance document entitled “Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions.”

5. Section 870.3800 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 870.3800 Annuloplasty ring.

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(b) *Classification*. Class II (special controls). The special control for this device is the FDA guidance document entitled “Guidance for Annuloplasty Rings 510(k) Submissions.”

6. Section 870.4230 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 870.4230 Cardiopulmonary bypass defoamer.

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(b) *Classification*. Class II (special controls). The special control for this device is the FDA guidance document entitled “Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions.”

7. Section 870.4260 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 870.4260 Cardiopulmonary bypass arterial line blood filter.

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(b) *Classification*. Class II (special controls). The special control for this device is the FDA guidance document entitled “Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions.”

8. Section 870.4350 is amended by revising paragraph (b) and by removing paragraph (c) to read as follows:

§ 870.4350 Cardiopulmonary bypass oxygenator.

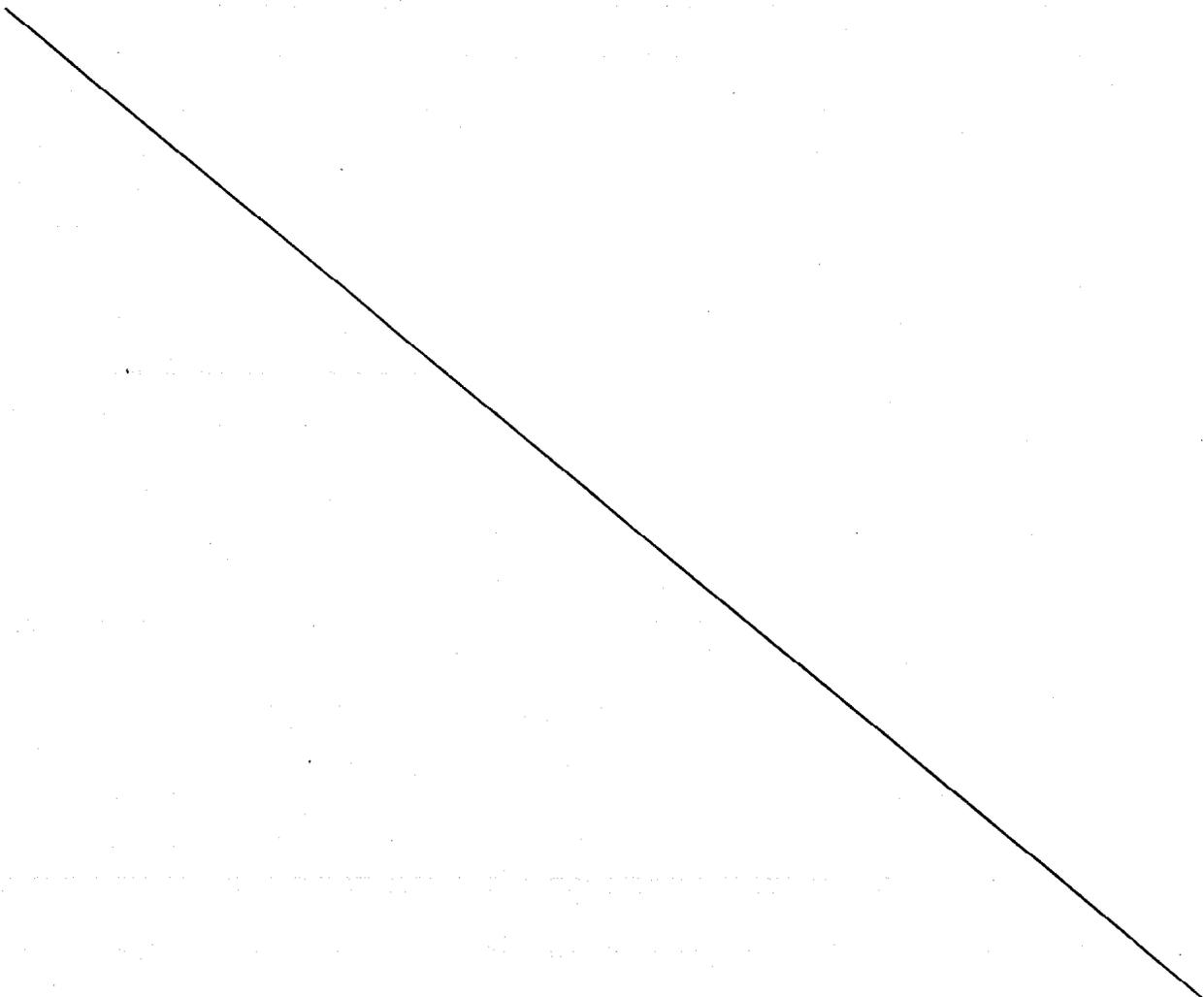
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(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled “Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions.”

PART 886—OPHTHALMIC DEVICES

9. The authority citation for 21 CFR part 886 continues to read as follows:

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



§ 886.3920 [Amended]

10. Section 886.3920 *Aqueous shunt* is amended in paragraph (a) by removing the word “neurovascular” and adding in its place the word “neovascular”.

Dated: 3/29/01
March 29, 2001.

Linda S. Kahan

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CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Monica Oliver

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