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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 00D-1086, 00D-1087, 00D-1088, 00D-1089, 00D-1090, and 00D-1091]

Guidance Documents for Premarket Notification (510(k)) Submissions for Six Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of six guidance documents. These six guidance documents are intended to serve as special controls for six devices that FDA has proposed previously to reclassify from class III (premarket approval) to class II (special controls). Elsewhere in this issue of the **Federal Register**, FDA is reopening the comment period on the proposed reclassification of the six devices and one other device. FDA is now inviting comment on these guidance documents because they were not available for comment at the time of the publication of the proposed reclassification (64 FR 12774, March 15, 1999).

DATES: Submit written comments by [*insert date 90 days after date of publication in the Federal Register*].

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number for the appropriate guidance document found in the

SUPPLEMENTARY INFORMATION section. Submit written requests for single copies on a 3.5" diskette of one or more of these guidance documents to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office

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in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance documents.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-827-2974.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 15, 1999, FDA published a proposed rule to reclassify 38 preamendments class III devices into class II and to establish special controls for these devices. 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 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) (62 FR 8961, February 27, 1997). The request further noted that it was impossible to comment on the proposed reclassification without the guidance documents being available. Therefore, the requester asked that FDA extend the comment period until at least 90 days after the guidance documents are publicly available. FDA agreed with the request. FDA also identified three additional devices for which the agency had not issued the guidance documents proposed as special controls in accordance with the GGP policy.

The agency is announcing the availability of the following six guidance documents (each with a separate docket number) for six of these nine devices. In the near future, FDA will announce the availability of two guidance documents that will address the other three devices.

The six guidance documents, with their docket numbers, and Facts-on-Demand (FOD) numbers are as follows:

Guidance Document	Docket No.	FOD No.	21 CFR Section	Device Name
Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions	00D-1086	372	870.3260	Pacemaker lead adaptor
Guidance Document for Vascular Prostheses 510(k) Submissions	00D-1087	1357	870.3450	Vascular graft prosthesis of less than 6 millimeter diameter
Guidance for Annuloplasty Rings 510(k) Submissions	00D-1088	1358	870.3800	Annuloplasty ring
Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions	00D-1089	1632	870.4230	Cardiopulmonary bypass defoamer
Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions	00D-1090	1622	870.4260	Cardiopulmonary bypass arterial line blood filter
Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions	00D-1091	1361	870.4360	Cardiopulmonary bypass oxygenators

These guidance documents represent the agency's current thinking on premarket notifications for these devices. These guidance documents do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both. Under FDA's GGP policy, each of these guidance documents is a Level 2 guidance.

II. Electronic Access

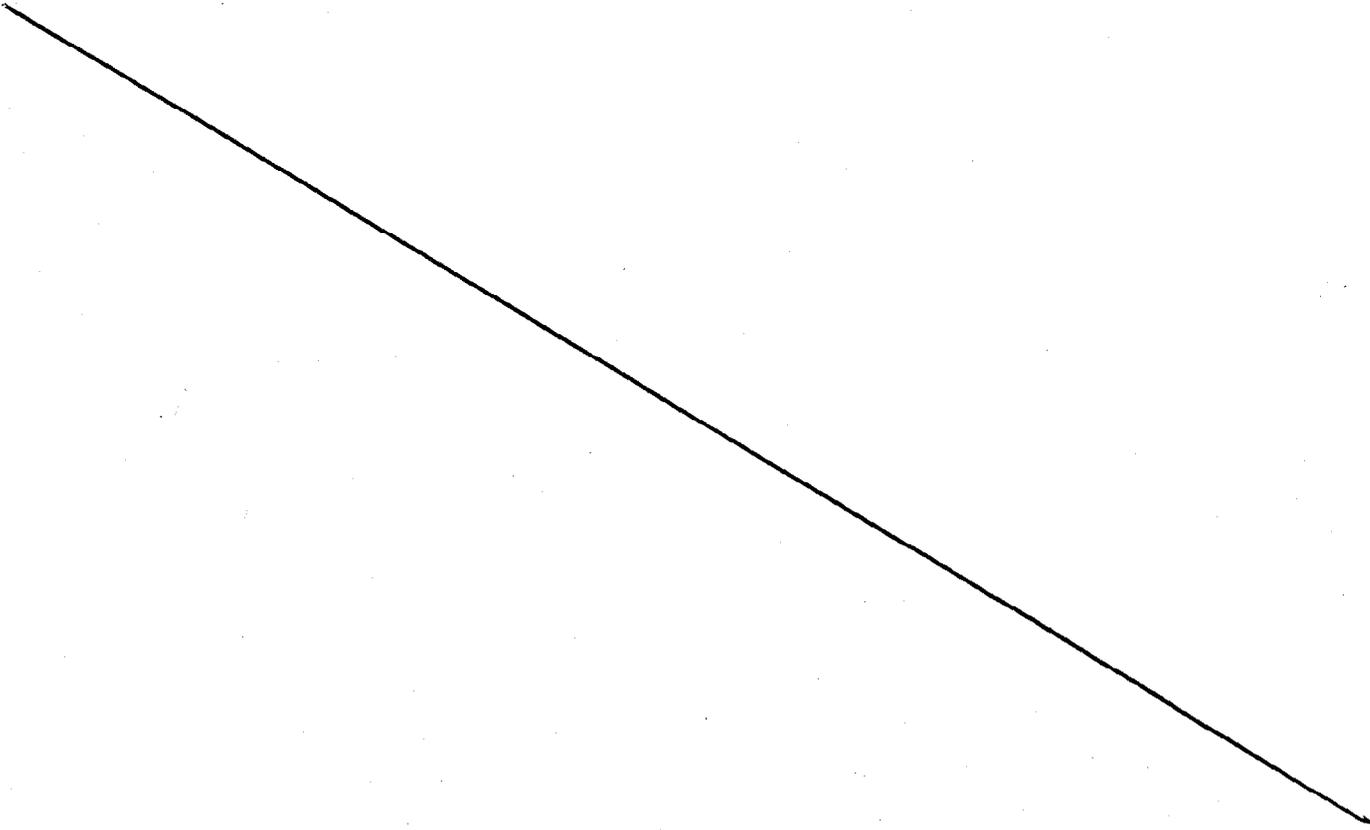
In order to receive these guidance documents via your fax machine, call the CDRH FOD system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system and enter the document number listed above followed by the pound sign (#). Follow the remaining voice prompts to complete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

Persons interested in obtaining a copy of these guidance documents may do so by using the Internet. CDRH maintains an entry 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** reprints, 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 information. 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>.

III. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding these guidance documents by *[insert date 90 days after date of publication in the Federal Register]*. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number for each guidance document as listed in the table in the **SUPPLEMENTARY INFORMATION** section of this document. If you wish to comment on more than one guidance document, please submit your comments



separately for each guidance document. The guidance documents and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 4/3/00
April 3, 2000

Linda S. Kahan

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Regulations Policy
Center for Devices and
Radiological Health

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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