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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 864, 866, 868, 870, 872, 874, 876, 878, 884, 886, and 888

[Docket No. 99N-0035]

Medical Devices; Reclassification of 38 Preamendments Class III Devices into Class II

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 90 days the comment period for the submission of comments regarding 6 of the 38 devices proposed for reclassification from class III into class II. The proposed rule was published in the **Federal Register** of March 15, 1999 (64 FR 12774). The agency is taking this action in part in response to a request for more time to submit comments to FDA regarding several of the guidance documents that were not made available when the March 15, 1999, proposed rule was published. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of these guidance documents for comment.

DATES: Submit written comments on the proposed rule 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.

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 (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. Interested persons were given until June 14, 1999, to comment on the proposed rule.

A trade association requested that FDA reopen the comment period for the following six devices: (1) Vascular graft prosthesis of less than 6 millimeters diameter, (2) pacemaker lead adaptor, (3) annuloplasty ring, (4) cardiopulmonary bypass defoamer, (5) cardiopulmonary bypass arterial line blood filter, and (6) cardiopulmonary bypass oxygenator. 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 the agency's Good Guidance Practices (GGP's). The request further noted that it was impossible to comment on the proposed reclassification without the guidance documents being available. Therefore, the trade association requested that FDA extend the comment period until at least 90 days after the guidance documents are publicly available for comment.

FDA also identified an additional three devices for which the agency had not issued the guidance documents proposed as special controls in accordance with the GGP policy: The indwelling blood carbon dioxide partial pressure (Pco²) analyzer, the indwelling blood hydrogen ion concentration (pH) analyzer, and the indwelling blood oxygen partial pressure (Po²) analyzer. In the near future, FDA intends to announce the availability of two guidance documents for these three devices and will reopen the comment period on the reclassification of those devices at that time.

Accordingly, FDA is reopening the comment period for the March 15, 1999, proposed rule to allow additional time for interested persons to comment on the following six devices:

Table 1

21 CFR Section	Device Name
870.3450 870.3620	Vascular graft prosthesis of less than 6 millimeters diameter Pacemaker lead adaptor

21 CFR Section	Device Name
870.3800 870.4230 870.4260 870.4350	Annuloplasty ring Cardiopulmonary bypass defoamer Cardiopulmonary bypass arterial line blood filter Cardiopulmonary bypass oxygenator

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the proposed rule only with respect to the six devices listed above 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 found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 7/3/00
April 3, 2000

Linda S. Kahan

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Center for Devices and
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