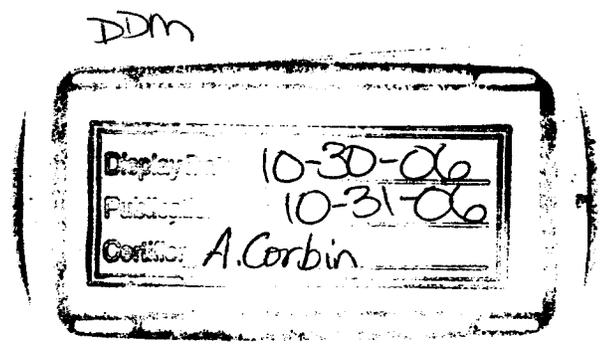


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0363]



**Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Absorbable Hemostatic Device; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Controls Guidance Document: Absorbable Hemostatic Device." The draft guidance describes a means by which the absorbable hemostatic device may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify the absorbable hemostatic device from class III (premarket approval) into class II (special controls). This draft guidance is not final, nor is it being implemented at this time.

**DATES:** Submit written or electronic comments on this draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Class II Special Controls Guidance Document: Absorbable Hemostatic Device" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send

one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-276-3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** David Krause, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090, ext. 141.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Absorbable hemostatic devices are primarily applied during surgical procedures in order to control bleeding that is not readily controlled via conventional means, such as cautery or ligation. At other times, an absorbable hemostatic device may be applied due to the inaccessibility of a site to conventional hemostatic methods.

On July 24, 2003, the General and Plastic Surgery Devices Panel considered the types of information the agency should include in a class II special controls guidance document for the absorbable hemostatic device and recommended that the device be reclassified from class III into class II. FDA considered the Panel's recommendations, and elsewhere in this issue of the **Federal Register**, is proposing to reclassify the absorbable hemostatic device into class II. If this reclassification rule is finalized, FDA intends that this guidance document will serve as the special control for this device.

Following the effective date of any final reclassification rule based on this proposal, any firm submitting a premarket notification (510(k)) for an absorbable hemostatic device would need to address the issues covered in the special controls guidance document. However, the firm need only show that its device meets the recommendations of the guidance document or in some other way provides equivalent assurances of safety and effectiveness.

## **II. Significance of Guidance**

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the absorbable hemostatic device. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## **III. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive the draft guidance document entitled "Class II Special Controls Document: Absorbable Hemostatic Device," you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document, or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1558 to identify the guidance you are requesting.

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 Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved submissions, approved applications, and manufacturers' addresses), small manufacturer's assistance,

information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

#### **IV. Paperwork Reduction Act of 1995**

This draft guidance contains information collection provisions that are subject to the review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

#### **V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 10/19/06  
October 19, 2006.

Linda S. Kahan  
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Center for Devices and Radiological Health.

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