

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 02D-0289]

### Medical Devices; Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA; Availability

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

**ACTION:** Notice.

---

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.” This guidance will serve as a special control for the absorbable polydioxanone surgical (PDS) suture which is being reclassified from class III to class II (special controls) elsewhere in this issue of the **Federal Register**. This guidance document is immediately in effect as the special control for the absorbable PDS suture, but it remains subject to comment in accordance with the agency’s good guidance practices (GGPs).

Also, elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to amend eight other surgical suture device classification regulations in order to designate this guidance as the special control for each such device. After public comments are reviewed, FDA intends to issue a final rule for the eight other surgical sutures and make this guidance effective as the special control guidance for those sutures in addition to the PDS suture, for a total of nine suture types. This guidance is not final nor is it in effect

at this time for the eight surgical sutures for which it is being proposed as a special control.

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

**ADDRESSES:** Submit written requests for single copies on a 3.5” diskette of the draft guidance document entitled “Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA” to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818.

Submit written comments concerning this guidance 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 found in brackets in the heading of this document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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

**SUPPLEMENTARY INFORMATION:**

## **I. Background**

This guidance document describes a means by which surgical suture devices may comply with the requirement of special controls for class II devices. Designation of this guidance document as a special control means that a manufacturer attempting to establish that its device is substantially equivalent to a predicate class II surgical suture should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness.

## **II. Significance of Guidance**

This guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The guidance represents the agency's current thinking on "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA." 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**

In order to receive "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA," via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1387) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so 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. Updated on a regular basis, the CDRH home page includes 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>. 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 Dockets Management Branch Internet site at <http://www.fda.gov/ohrms/dockets>.

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

This guidance contains information collection provisions that are subject to 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 in 21 CFR part 807, subpart E were approved under OMB control number 0910–0120.

#### **V. Comments**

You may submit to Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance by [*insert date 90 days after date of publication in the Federal Register*]. You should submit two copies of any comments. Individuals may submit one copy.

You must identify comments with the docket number found in brackets in the heading of this document. The guidance document and comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 16, 2002.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

**BILLING CODE 4160-01-S**