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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 02N-0288]

Medical Devices; Designation of Special Control for Eight Surgical Suture Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to amend the classification regulations for eight surgical suture devices previously reclassified into class II to specify a special control for those devices. The special control is an FDA guidance document entitled "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" that identifies performance, testing, and labeling recommendations for the devices. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control. FDA is taking these actions on its own initiative because it believes they are necessary to provide reasonable assurance of the safety and effectiveness of surgical suture devices. These actions are being taken under the Federal Food, Drug, and Cosmetic Act (the act).

DATES: This rule is effective July 3, 2003.

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, ext. 164.

SUPPLEMENTARY INFORMATION:

I. Background

The act (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101-629), the Food and Drug Administration Modernization Act (FDAMA) (Public Law 105-115), and the Medical Device User Fee and Modernization Act (MDUFMA) (Public

Law 107-250) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under the 1976 amendments, class II devices were defined as those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish performance standards to provide such assurance.

SMDA broadened the definition of class II devices to mean those devices for which the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act).

The 1976 amendments also broadened the definition of "device" in 201(h) of the act (21 U.S.C. 321(h)) to include certain articles that were once regulated as drugs. Under the 1976 amendments, Congress classified into class III all transitional devices, i.e., those devices previously regulated as new drugs, including surgical sutures.

II. Regulatory History of the Devices

In the **Federal Register** of December 16, 1977 (42 FR 63472), FDA published a notice that identified sutures as class III devices under the transitional provisions of the act. Section 520(l)(2) of the act (21 U.S.C. 360j(l)(2)) provides that the manufacturer or importer of a device classified in class III under the transitional provisions may file a petition for reclassification of the device into class I or class II. Procedures for filing and review of classification petitions are set forth in § 860.136 (21 CFR 860.136).

In accordance with section 520(l)(2) of the act and § 860.136, and after consulting with members of the General and Plastic Surgery Devices Panel, FDA reclassified surgical suture devices from class III to class II as follows:

1. Absorbable poly(glycolide/L-lactide) surgical suture (21 CFR 878.4493), reclassification order (letter) dated September 14, 1989;

2. Stainless steel suture (21 CFR 878.4495), reclassification order (letter) dated July 30, 1986;

3. Absorbable surgical gut suture (21 CFR 878.4830), reclassification order (letter) dated September 19, 1988;

4. Nonabsorbable poly(ethylene terephthalate) surgical suture (21 CFR 878.5000), reclassification order (letter) dated July 5, 1990;

5. Nonabsorbable polypropylene surgical suture (21 CFR 878.5010), reclassification order (letter) dated July 5, 1990;

6. Nonabsorbable polyamide surgical suture (21 CFR 878.5020), reclassification order (letter) dated February 15, 1990;

7. Natural nonabsorbable silk surgical suture (21 CFR 878.5030), reclassification order (letter) dated November 9, 1990; and

8. Nonabsorbable expanded polytetrafluoroethylene surgical suture (21 CFR 878.5035), reclassification order (letter) dated September 9, 1999.

In the **Federal Register** of December 19, 2002 (67 FR 77678), FDA published a proposed rule to designate a special control for eight surgical suture devices already classified into class II. FDA proposed that surgical suture devices would remain in class II, but would be subject to a special control. The proposed rule identified the special control as an FDA guidance document entitled "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA." In the same edition of the **Federal Register**, FDA announced the availability of the draft guidance that, when final, was intended to serve as a special control (67 FR 77797). FDA invited interested persons to comment on the proposed rule and on the proposed special control guidance document by March 19, 2003.

III. FDA's Conclusion

FDA received no comments on the proposed rule or on the guidance document proposed as the special control. Therefore, under the SMDA authority, FDA is amending the classification regulations for eight surgical suture devices previously reclassified into class II, to designate a special control for those devices. The special control capable of providing reasonable assurance of safety and effectiveness for these devices is a guidance document entitled "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" that identifies performance,