

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 878

[Docket No. 86P-0087]

Medical Devices; Reclassification and Codification of the Stainless Steel Suture

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has issued an order in the form of a letter to Alto Development Corp. (the petitioner) reclassifying the 316L stainless steel suture for use in abdominal wound closure, intestinal anastomosis, hernia repair, and sternal closure from class III (premarket approval) to class II (special controls). The order is being codified in the Code of Federal Regulations (CFR). Although FDA reclassified the device in 1986, it inadvertently neglected to publish a notice of the reclassification in the **Federal Register** or codify the change in the CFR.

DATE: This rule is effective *[insert date 30 days after date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Stephen P. Rhodes, 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

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *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 (the SMDA) (Public Law 101-629), and the Food and Drug

Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115), 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. The SMDA broadened the definition of class II devices to mean 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 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 broadened the definition of "device" in section 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 all transitional devices, i.e., those devices previously regulated as new drugs, including stainless steel sutures, into class III.

On December 16, 1977, FDA published a notice in the **Federal Register** (42 FR 63472), that identified sutures as class III devices under the transitional provisions of the act for which premarket approval is required. Section 520(1)(2) of the act (21 U.S.C. 360j(1)(2)) provides that, in addition to the Secretary of Health and Human Services, the manufacturer or importer of a device classified into class III under the transitional provisions, may file a petition for reclassification of the device into class I or class II. The procedures for filing and review of petitions for reclassification of transitional devices are set forth in § 860.136 (21 CFR 860.136).

On February 21, 1986, FDA filed the petition submitted by the petitioner, requesting reclassification of the 316L stainless steel sutures from class III to class II. FDA consulted with the General and Plastic Surgery Devices Panel (the Panel) regarding reclassification of the devices. During an open panel meeting on March 25, 1986, the Panel recommended that FDA reclassify the 316L stainless steel sutures intended for use in abdominal wound closure, intestinal anastomosis, hernia repair, and sternal closure, from class III to class II. In addition, the Panel recommended that FDA assign a low priority for the development of a performance standard based on the long history of safe use of the device and the conformance by stainless steel manufacturers to existing voluntary standards.

After reviewing the data in the petition and presented before the Panel, FDA agreed with the Panels recommendation that the 316L stainless steel sutures, and substantially equivalent devices of this generic type, intended for use in abdominal wound closure, intestinal anastomosis, hernia repair, and sternal closure should be reclassified from class III to class II, and that the issuance of a performance standard for the device would be a low priority.

On July 30, 1986, FDA issued an order to the petitioner reclassifying the 316L stainless steel suture, and substantially equivalent devices for this generic type, from class III into class II. Inadvertently, FDA neglected to announce the reclassification order in the **Federal Register**.

Accordingly, as required by § 860.136(b)(6), FDA is announcing the reclassification of the generic 316L stainless steel suture from class III to class II. In addition, FDA is issuing this final rule to codify the reclassification of the device by adding new § 878.4495.

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the device from class III to class II has relieved all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act (21 U.S.C. 360e). Because reclassification has reduced regulatory costs with respect to this device, no significant economic impact has been imposed on any small entities, and it may have permitted small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this final rule does not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

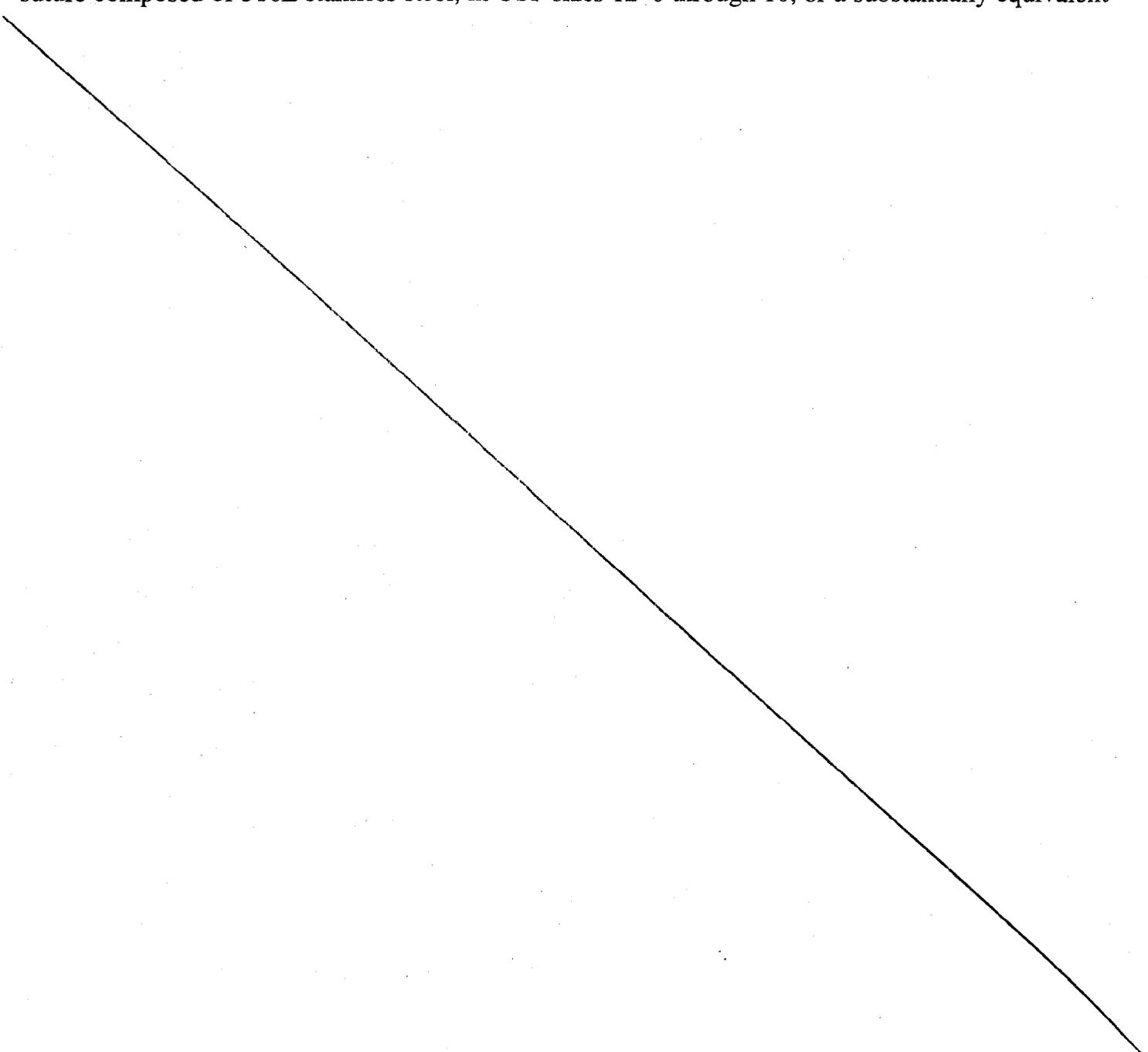
1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Section 878.4495 is added to subpart E to read as follows:

§ 878.4495 Stainless steel suture.

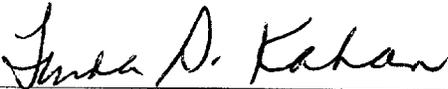
(a) *Identification.* A stainless steel suture is a needled or unneedled nonabsorbable surgical suture composed of 316L stainless steel, in USP sizes 12-0 through 10, or a substantially equivalent



stainless steel suture, intended for use in abdominal wound closure, intestinal anastomosis, hernia repair, and sternal closure.

(b) *Classification*. Class II (special controls).

Dated: 3/29/00
March 29, 2000



Linda S. Kahan
Deputy Director for
Regulations Policy
Center for Devices and
Radiological Health

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