DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 4 2001

Mr. Gregory R. Jones
Director, Regulatory Affairs
Ethicon, Inc.
P.O. Box 151
Somerville, New Jersey 08876-0151

Re: Reclassification Order:
Docket No. 99P-5589
Reclassification of the Absorbable Polydioxanone Surgical Suture

Dear Mr. Jones:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for reclassification of the absorbable polydioxanone surgical suture that is intended for use in soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery. FDA concludes that this device and substantially equivalent devices of this generic type, should be reclassified from class III into class II. This order, therefore, reclassifies the absorbable polydioxanone surgical suture, and substantially equivalent devices of this generic type into class II, under the generic name absorbable polydioxanone surgical suture, effective immediately. This order also identifies the special controls applicable to the device as the FDA guidance document "Class II Special Controls Guidance Document: Guidance for Surgical Suture 510(k)s; Final Guidance for Industry" (FDA guidance document). You do not need to submit a premarket notification submission (510(k)) for your absorbable polydioxanone surgical suture, and you may continue to market you absorbable polydioxanone surgical suture as described in your reclassification petition.

FDA identifies this generic type of device, the subject of this reclassification, as follows: An absorbable polydioxanone surgical suture is an absorbable, flexible, sterile, monofilament thread prepared from polyester polymer poly(p-dioxanone) and is intended for use in soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery. It may be coated or uncoated; undyed or dyed; and with or without a standard needle attached.

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et. seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94-295), the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101-629), and the Food and Drug Administration Modernization Act of 1997 (the FDAMA) (Pub. L. 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).

The 1976 amendments 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 all transitional devices, i.e., those devices previously regulated as new drugs, including the absorbable polydioxanone surgical suture, into class III. The legislative history of the SMDA reflects congressional concern that many transitional devices were being overregulated in class III (H. Rept. 808, 101st Cong., 2d sess. 26-27 (1990); S. Rept. 513, 101st Cong., 2d sess. 27 (1990)). Congress amended section 520(l) of the act (21 U.S.C. 360j(l)) to direct FDA to collect certain safety and effectiveness information from the manufacturers of transitional devices still remaining in class III to determine whether the devices should be reclassified into class II (special controls) or class I (general controls). Accordingly, in the Federal Register of November 14, 1991 (56 FR 57960), FDA issued an order under section 520(l)(5)(A) of the act, requiring manufacturers of transitional devices, including the absorbable polydioxanone surgical suture, to submit to FDA a summary of, and a citation to, any information known or otherwise available to them respecting the devices, including adverse safety or effectiveness information which had not been submitted under section 519 of the act (21 U.S.C. 360i). Manufacturers were to submit the summaries and citations to FDA by January 13, 1992. However, because of misunderstandings and uncertainties regarding the information required by the order, and whether the order applied to certain manufacturers' devices, many transitional class III device manufacturers failed to comply with the reporting requirement by January 13, 1992. Consequently, in the Federal Register of March 10, 1992 (57 FR 8462), FDA extended the reporting period to March 31, 1992.

Section 520(l)(5)(B) of the act provides that, after the issuance of an order requiring manufacturers to submit a summary of, and citation to, any information known or otherwise available respecting the devices, but before December 1, 1992, FDA was to publish regulations either leaving transitional class III devices in class III or reclassifying them into class I or II. Subsequently, as permitted by section 520(l)(5)(C) of the act, in the Federal Register of November 30, 1992 (57 FR 56586), the agency published a notice extending the period for issuing such regulations until December 1, 1993. Due to limited resources, FDA was unable to publish the regulations before the December 1, 1993 deadline.

As you know, on August 25, 1999, FDA filed your petition requesting reclassification of the absorbable polydioxanone suture from class III into class II. The petition was submitted under section 520(l)(2) of the act (21 U.S.C. 360j(l)(2)), and 21 CFR 860.136 of the agency's regulations. In accordance with section 520(l)(1) of the act, the absorbable polydioxanone surgical suture was automatically classified into class III because the absorbable polydioxanone surgical suture was a transitional device. In order to reclassify the absorbable polydioxanone surgical suture intended for use in soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and in ophthalmic surgery into class II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of safety and effectiveness of the device for its intended use.

Pursuant to 21 CFR 860.125 and 860.136(b)(5), FDA consulted with members of the General and Plastic Surgery Devices Panel (the Panel). The Panel members recommended that the absorbable polydioxanone surgical suture for use in soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and in ophthalmic surgery be reclassified from class III into class II because they believe that special controls will provide reasonable assurance of the safety and effectiveness of the device. This recommendation was based on the information and data contained in the reclassification petition, on the summary and analysis of the data as set forth in the petition, and on their personal knowledge of, and clinical experience with, the device. The Panel members also recommended that the special controls to reasonably assure the safety and effectiveness of the device be FDA recognized consensus standards and device-specific labeling.

FDA identified the following risks to health associated with the use of the device: suture breakage causing wound dehiscence, tissue inflammatory response, wound infection, and toxicological and pharmacological issues associated with suture absorption. FDA believes that these risks to health can be controlled by adherence to the FDA guidance document.

After review of the information submitted in the petition, and consultation with the Panel members, FDA has determined that the absorbable polydioxanone surgical suture intended for use in soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and in ophthalmic surgery, as described and identified herein can be reclassified from class III into class II with the establishment of special controls. FDA believes that all information encompassed by the special controls recommended by the Panel members is contained in the FDA guidance document. FDA believes that class II, with special controls provide reasonable assurance of the safety and effectiveness of the device.

Therefore, FDA is reclassifying the absorbable polydioxanone surgical suture intended for use in soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and in ophthalmic surgery, and substantially equivalent devices of this type into class II. The device is subject to all the general controls of the act and the special controls identified under section 513(a)(1)(B) of the act (21 U.S.C. 360c(a)(1)(B)); namely adherence to the FDA guidance document. Thus, persons who intend to market this device must submit to FDA a premarket notification submission for their absorbable polydioxanone surgical suture prior to marketing the device and receive a substantial equivalence determination from the agency to market their product.

A notice announcing this reclassification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

If you have any questions concerning this reclassification order, please contact Mr. Anthony D. Watson at (301) 594-3090. Thank you for your cooperation throughout the reclassification process.

Sincerely yours,

Philip J. Phillips
Deputy Director for Science
and Regulatory Policy
Office of Device Evaluation
Center for Devices and
Radiological Health