DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

OCT 16 2007

John D. Paulson, Ph.D.
Vice President, Regulatory Affairs
Ethicon, Incorporated
Route 22 West
Somerville, New Jersey 08876

Re: K955646
Trade Name: Vicryl Peridontal Mesh
Regulation Number: 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: 2
Product Code: NPK
Dated: March 27, 1996
Received: March 28, 1996

Dear Dr. Paulson:

This letter corrects our substantially equivalent letter of May 20, 1996.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Protecting and Promoting Public Health

K955646

MAY 20 1996

SECTION 7

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary of Safety and Effectiveness	Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency. NEW DEVICE NAME: VICRYL (polyglactin 910) Periodontal Mesh PREDICATE DEVICE NAME: GORE-TEX^{R} Periodontal Material

510(k) SUMMARY

Device Description	VICRYL periodontal mesh is prepared from a synthetic, bioabsorbable copolymer of glycolide and lactide. The woven mesh is prepared from undyed strands identical to the strands used in VICRYL (polyglactin 910) synthetic, bioabsorbable suture. VICRYL periodontal mesh is provided sterile, available in various sizes and shapes each with synthetic, bioabsorbable VICRYL ligatures affixed to the barrier.
Intended Use	VICRYL periodontal mesh is intended for use as a barrier to provide temporary support during the early stages of the healing process following periodontal surgery.

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510(k) SUMMARY, Continued

Indications Statement	VICRYL periodontal mesh is a bioabsorbable implantable material intended to aid in the healing of periodontal defects.
Technological Characteristics	The new device provides a membrane barrier to apical migration of gingival epithelium during a period of periodontal ligament regeneration. Unlike the predicate device, the new device does not need to be removed post-implantation.
Performance Data	Analytical characterization to assess thermal properties and molecular weight was conducted. Preclinical laboratory and clinical evaluations were conducted to ensure that the device functioned as intended. Sufficient data has been gathered from preclinical and clinical testing to assess the safety and effectiveness of the new device.
Conclusions	Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Device under the Federal Food, Drug, and Cosmetic Act.
Contact	John D. Paulson, Ph.D. Director, Regulatory Affairs ETHICON, Inc. Rt. #22, West Somerville, NJ 08876-0151
Date	December 8, 1995