Péters SURGICAL

OCT - 2 2006

SECTION 11

510(k) SUMMARY

[As Required by 21 CFR 807.92(c)]

Information supporting claims of substantial equivalence, as defined under the Federal Food, drug and Cosmetic Act, respecting safety and effectiveness is summarized below.

510(k) Summary Date prepared August 8, 2006

510(k) Submitter

PETERS SURGICAL
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Official Correspondent

Annie LASSERRE
Research & Development Manager
PETERS SURGICAL Bobigny, FRANCE, 93013
Phone: 33-148-106259

New Device Name

Trade name:	OPTIME® and SINUSORB® PGA
Common/Usual name:	Synthetic Absorbable Suture, PGA Suture
Classification name:	Suture, Absorbable, Synthetic, Polyglycolic Acid

New Device Classification Class II in 21 CFR §878.4493 by the General and Plastic Surgery Devices Panel, Absorbable poly(glycolide/l-lactide) surgical suture (GAM).

Predicate Device Name Coated VICRYL™ (POLYGLACTIN 910) Suture, ETHICON INC., K022269.

Statement of intended use

The synthetic absorbable surgical sutures OPTIME® and SINUSORB® PGA are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery; but not for use in cardiovascular and neurological surgery.

OPTIME® and SINUSORB® PGA have the same intended use as the predicate device Coated VICRYL™ (Polyglactin 910) Suture.

New Device Description

OPTIME® and SINUSORB® PGA are synthetic absorbable braids composed of homopolymer of glycolic acid and coated with epsilon-caprolactone and calcium stearate or a mixture composed of polycaprolacton, calcium stearate and fatty acid ester. These surgical sutures are available undyed or violet dyed with an FDA approved color additive: D&C violet n°2, CI 60725. The suture may be provided with or without a standard needle attached.

Summary of Technological Characteristics of New Device compared to Predicate Device

OPTIME® and SINUSORB® PGA sutures have similar technological characteristics as the predicate device Coated VICRYL™ (Polyglactin 910) Suture. Like the predicate device, OPTIME® and SINUSORB® PGA are sterile, braided synthetic absorbable surgical sutures that conform to the requirements of the United States Pharmacopoeia (USP) and the European Pharmacopoeia (EP) for Absorbable surgical sutures. The polyglycolic acid material used for both "new" and "predicate" medical devices is commonly used in surgical applications and has been proven to be biocompatible.

Performance data

Non-clinical laboratory testing was performed demonstrating that the device complied with the USP Monographs and with the EP Monographs for Absorbable surgical sutures.

Conclusions

Based on the 510(k) summary (21 CFR 807) and the information provided herein, we conclude that our New Medical Devices OPTIME® and SINUSORB® PGA are substantially equivalent to the Predicate device Coated VICRYL™ Suture under the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2006

Peters Surgical
% Ms. Annie Lasserre
Research and Development Manager
Z.I. Les vignes
42 Rue Benoît Frachon
Bobigny, France 93013

Re: K062366
Trade/Device Name: OPTIME®, SINUSORB® PGA
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly (glycolide/L-lactide) surgical suture
Regulatory Class: Class II
Product Code: GAM
Dated: August 8, 2006
Received: August 14, 2006

Dear Ms. Lasserre:

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 application (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 such 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 begin 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/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 10

STATEMENT OF INDICATIONS FOR USE

510(k) Number K062366

Device Name OPTIME®, SINUSORB® PGA

Indications for use

The synthetic absorbable surgical sutures OPTIME® and SINUSORB® PGA are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery; but not for use in cardiovascular and neurological surgery.

Prescription Use _x_ AND/OR Over-The-Counter Use ____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062366