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DEC 13 2005

SECTION 10

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

September 12, 2005

510(k) Submitter

PETERS SURGICAL
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42 rue benoit frachon
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Phone: 33-148-106262
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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:	COROLENE®
Common/Usual name:	Surgical suture, Polypropylene
Classification name:	Nonabsorbable Polypropylene Surgical Suture

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New Device Classification

Class II in 21 CFR §878.5010 by the General and Plastic Surgery Devices Panel, Nonabsorbable Polypropylene Surgical Suture (GAW).

Predicate Device Name

PROLENE™, Nonabsorbable Polypropylene Surgical Suture (N16374).

Statement of intended use

COROLENE® sutures are intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular and vascular surgery, in ophthalmic surgery, in plastic surgery and in neurological surgery.

COROLENE® has the same intended use as the predicate device PROLENE®.

New Device Description

COROLENE® is a monofilament synthetic non-absorbable surgical suture composed of polypropylene. The suture is available undyed or blue dyed with an FDA approved color additive: Phtalocyanine-copper (CI 74160), to enhance visibility. The suture may be provided with or without a standard needle attached.

Summary of Technological Characteristics of New Device compared to Predicate Device

Our new device COROLENE® has similar technological characteristics as the predicate device PROLENE®. Like currently marketed PROLENE® suture, COROLENE® is a sterile monofilament synthetic non-absorbable surgical suture that conforms to the requirements of the United States Pharmacopoeia (USP) and the European Pharmacopoeia (EP) for non-absorbable surgical sutures. The polypropylene material used for both medical devices is commonly used in surgical applications and has been proven to be biocompatible.

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Performance data

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

Conclusions

Based on the 510(k) summary (21 CFR 807) and the information provided herein, we conclude that our New Medical Device COROLENE® is substantially equivalent to the Predicate Device PROLENE® 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

DEC 13 2005

Annie Lasserre
R & D Manager
Peters Surgical
Z.I Les vignes
42 Rue Benoit Frachon
Bobigny, France 93013

Re: K052701
Trade/Device Name: COROLENE®
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable poly-propylene surgical suture
Regulatory Class: II
Product Code: GAW
Dated: September 6, 2005
Received: September 28, 2005

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

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

Enclosure

K052701

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SECTION 9

STATEMENT OF INDICATIONS FOR USE

510(k) Number _____

Device Name COROLENE®

Indications for use

COROLENE® sutures are intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular and vascular surgery, in ophthalmic surgery, in plastic surgery and in neurological surgery.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (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)

Barbara Bruen MD

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

510(k) Number K052701