K060163 1/3

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Attachment 12

OCT 1 1 2006

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

January 09, 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

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New Device Name

Trade name:	CARDIOFLON®, CARDIOXYL®
Common/Usual name:	Sterile Polyester Suture
Classification name:	Polyester Nonabsorbable Synthetic Suture

New Device Classification

Class II by the General and Plastic Surgery Devices Panel, Nonabsorbable Polyester Surgical Suture (GAS).

Predicate Device Name

PETERS CARDIOFLON® SUTURE, Nonabsorbable Polyester Synthetic Suture (K913101).
TI•CRON™, Nonabsorbable Polyethylene Surgical Suture (K930591).

Statement of intended use

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

New Device Description

The synthetic non-absorbable surgical sutures CARDIOFLON® and CARDIOXYL® are composed of a polyester [poly(ethylene terephtalate)] braids, with or without PLEDGET of different sizes. CARDIOFLON® braids are coated with a polymer of tetrafluorethylene (PTFE) and CARDIOXYL® braids are coated with polysiloxane.

CARDIOFLON® and CARDIOXYL® sutures are green dyed (D&C green n°6 CI 61565) and white (undyed). Some packs are composed of green and white braids to facilitate location during use.

CARDIOFLON® and CARDIOXYL® sutures comply with the requirements of the United States Pharmacopoeia (USP) and the European Pharmacopoeia (EP) for non-absorbable surgical sutures.

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Summary of Technological Characteristics of New Device to Predicate Device

CARDIOFLON® and CARDIOXYL® sutures have similar technological characteristics as the predicate devices and TI•CRON™. Like our previously cleared Polyester sutures PETERS CARDIOFLON® SUTURE and the currently marketed TI•CRON™ sutures, CARDIOFLON® and CARDIOXYL® are sterile synthetic non-absorbable surgical sutures that conform to the requirements of the United States Pharmacopoeia (USP) and the European Pharmacopoeia (EP) for non-absorbable surgical sutures. The polyester [poly(ethylene terephtalate)] material used for these 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 devices 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 CARDIOFLON® and CARDIOXYL® are substantially equivalent to the predicate devices PETERS CARDIOFLON® SUTURE and TI•CRON™ 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 11 2006

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

Re: K060163
Trade/Device Name: CARDIOFLON®, CARDIOXYL®
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT
Dated: August 29, 2006
Received: September 11, 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

K060163

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Attachment 10

Indications for Use Statement

510(k) Number (if known)	K060163
Device Name	CARDIOFLON® , CARDIOXYL®
Indications for Use	The CARDIOFLON® and CARDIOXYL® sutures are intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular surgery, in ophthalmic surgery and in neurological surgery.

Prescription Use ___×___ OR Over-The-Counter Use _____
(Per 21 CFR 801. 109)

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 K060163