K07 2863
pg 1 of 2

510(k) SUMMARY

MAY 23 2008

This Summary of 510(k) safety and effectiveness information is being submitted in accordance with the requeriments of SMDA 1990 and 21 CFR§807.92

The assigned 510(k) number is:

Submitter's identification:

Internacional Farmacéutica, S.A. de C.V.
Carreteraco 44 Col. Párque San Andrés Coyoacán
C.P. 04040 México, D.F.
Contact:
Mr. Alejandro von Mohr, General Director
Phone: (52 55) 55 44 87 60 to 62 ext. 227, 219
Fax: (52 55) 55 49 42 34

US Contact:
Mr. Alan P. Schwartz
55 Northern Boulevard
Great Neck, New York 11021
Phone: 516-482-9001
Fax: 516-482-0186

Date Summary prepared: May 31, 2007

Trade Name of the Device:

Atramat® PGC25 Poly(glycolide-co-epsilon-caprolactone) Surgical Sutures

Common or Usual Name:

Poly(glycolide-co-epsilon-caprolactone) Surgical Sutures

Classification of Device:

Class II in 21 CFR § 878.4493, Absorbable poly(glycolide/l-lactide) Surgical Suture

Classification Panel:

General & Plastic Surgery Devices Panel

Product Code:

GAM

Predicate Devices:

Monocryl* (poliglecaprone 25) Suture
(K960653 and K964072)

Device Description

Atramat® PGC25 Poly(glycolide-co-epsilon-caprolactone) Surgical Suture are synthetic absorbable sterile monofilament surgical sutures composed from a copolymer of glycolide and epsilon-caprolactone. This product is offered as undyed or dyed with an FDA listed color additive, D&C Violet No. 2.

K072863
pg 2 of 2

Intented Use:

Atramat® PGC25 Poly(glycolide-co-epsilon-caprolactone) Surgical Sutures are indicated for use as absorbable sutures in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

Summary of Thechnological Characteristics, comparison to predicate device

Atramat® PGC25 Poly(glycolide-co-epsilon-caprolactone) Surgical Sutures have similar technological characteristics as the predicate device. Like the predicate device, Atramat® PGC25 Poly(glycolide-co-epsilon-caprolactone) Surgical Sutures are sterile, monofilament synthetic absorbable surgical sutures that conform to the requeriments of United States Pharmacopoeia (USP), except for diameter, and Mexicans United States Farmacopoeia, Medical Devices Supplement (FEUM) for absorbable surgical sutures. The poly(glycolide-co-epsilon-caprolactone) material used for both "new" and "predicate" medical devices is commonly used in surgical applications and has been proven to be biocompatible. *In-vivo/in vitro* testing was provied showing that the device performed as intended and as claimed.

Discussion of Clinical Test Performed:

No clinical trials were conducted.

Conclusions

Based on the technological characteristics and physical properties of the Poly(glycolide-co-epsilon-caprolactone) sutures, the description, the intented use of the device and conformance with the following performance standars like:
USP 30
ISO 9001 and ISO 13485
FDA Guidance for Surgical Suture 510(k)

Internacional Farmaceutica believes that the subject devices demonstrate a substantial equivalence to the predicate devices and are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2008

Internacional Farmaceutica S.A. de C.V.
% mdi Consultants, Inc.
Mr. Alan P. Schwartz
55 Northern Boulevard
Great Neck, New York 11021

Re: K072863
Trade/Device Name: Atramat® PGC25 Poly(glycolide-co-epsilon-caprolactone) surgical sutures
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/L- lactide)surgical suture
Regulatory Class: II
Product Code: GAM
Dated: May 01, 2008
Received: May 22, 2008

Dear Mr. Schwartz:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

K072863

ATTACHMENT # 3

510(k) Number (if known):

Device Name: Atramat® PGC25 Poly(glycolide-co-epsilon-caprolactone) Surgical Sutures

Indications for Use:

Atramat® PGC25 Poly(glycolide-co-epsilon-caprolactone) Surgical Sutures are indicated for use as absorbable sutures in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

Prescription use ___X_____ (Per 21 CFR 801.109)

Over-The Counter Use _____ OR (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogden for MKN

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

510(k) Number K072863