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Exhibit #2
K040282

510(K) SUMMARY

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

The assigned 510(k) number is: K040282

1. **Submitter's identification:**

Internacional Farmaceutica S. A. de C.V.
Carreteraco 44 Col. Parque San Andrés Coyoacan 04040
México D.F.
Contact: Alejandro von Mohr, General Director
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Date Summary prepared: April 23, 2004

2. **Name of the Device:**

Trade Name:
Atramat ® Polyglycolic Acid
sorb-FAST ® Polyglycolic Acid

Common or Usual Name:
Polyglycolic Acid Surgical Suture

Classification Name:
Atramat ® Polyglycolic Acid and sorb-FAST ® Polyglycolic Acid based sutures are not specifically categorized or defined in 21CFR, parts 800-1299, the responsible device panel provided the following class, classification panel and product code for this product.

Device Class:
Class II

Classification Panel:
General & Plastic Surgery Devices Panel

Product Code:
79GAM

3. **Predicate Device Information:**

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Atramat ® Polyglycolic Acid Absorbable suture is substantially equivalent to the following absorbable suture marketed by Davis & Geck:

DEXON II® Polyglycolic Acid Synthetic Absorbable Surgical Sutures with Polycaprolactone Coating System. **(K972566) and Ethicon Absorbable Poly (L-lactide/glycolide) Surgical Sutures with Poliglactina 370 and Calcium Stearate Coating System (K964345).**

With respect to substantial equivalence, the comparation device represents a virtually identical device. Materials, packaging, sterilization method, sizes, multi and monofilament, dyed and undyed as well as functional characteristics (absorption rate, strength, diameter, etc) equivalence can also be drawn with respect to the design, material composition, performance and intended use, Atramat ® and Dexon II both meet or exceed the performance requirements of USP 24.

sorb-FAST® Polyglycolic Acid Absorption sutures are substantially equivalent to the following absorbable suture marketed by Ethicon (K962480 and K944110) , Vicryl Rapide® is prepared with a mixture of copolymer of glycolide and L-lactide with Poliglactin 370 and Calcium Stearate Coating System.

With respect to substantial equivalence, the predicate device represents a virtually identical device. Materials, packaging, sterilization method, sizes, multifilament, dyed and undyed as well as functional characteristics. Equivalence also demonstrated in material composition, performance, and intended use. Sorb-FAST® and Vicryl Rapide® both meet or exceed the performance requirements of USP 26.

4. **Device Description:**

Atramat® Polyglycolic Acid and sorb-FAST® Polyglycolic Acid are synthetic absorbable sterile surgical sutures composed of a synthetic polyglycolic acid polymer.

Atramat® Polyglycolic acid and sorb-FAST® Polyglycolic Acid meet all requirements as described in the United States Pharmacopeia (USP) monograph for Absorbables Surgical Sutures. These products are offered as monofilament or multifilament and it is offered uncoated or coated with polycaprolactone and calcium sterarate, it could also be undyed or dyed with D&C Violet No. 2.

Sizes offered are U.S.P. 8-0 through 2 (metric equivalent 0.4 through 5). The following table illustrates the sizes offered.

USP Size (Metric Size)
8.0 (0.4)
7.0 (0.55)
6.0 (0.7)

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5.0 (1)
4.0 (1.5)
3.0 (2)
2.0 (3)
0 (3.5)
1 (4)
2 (5)

Materials: Polyglycolic acid. USP & Polycaprolactone and Calcium Stearate

5. Intended Use:

Atramat ® Polyglycolic Acid Sutures are indicated for use as absorbable sutures in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

sorb-FAST ® Polyglycolic Acid Sutures are indicated only for use in superficial general soft tissue approximation of the skin and mucosa, where only short term wound support (7-10 days) is required. These sutures are not intended for use in ligation, ophthalmic, cardiovascular or neurological procedures.

6. **Comparison to Predicate Devices:**

	Atramat® Polyglycolic acid	**Predicate Device**
Intended Use	General soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.	Same Intended Use
Suture Material	Composed of glycolide polimer	Davis & Geck: composed of glycolide polymer
Suture Characteristics	Retains approximately 70% of its original tensile strength at two weeks post implantation, with approximately 50% remaining at three weeks. Absorption of the suture is essentially complete between 60 and 90 days.	Same
Sterilization Method	Ethylene Oxide gas	Same
Suture Diameter, Suture length, knot pull tensile, Strength and needle attachment strength	Meets or exceeds the performance requirements for " Absorbable Surgical Suture" as defined in the official Monograph of the United States Pharmacopoeia (USP) 24	Meet USP requirements
Packaging	Dry packaged in Aluminum Foil and	Same or equivalent

	polyester tear open	manner

	Sorb-FAST® Polyglycolic Acid	Predicate Device
Intended Use	Indicated only for use as absorbable sutures in superficial general soft tissue approximation of the skin and mucosa, where only short term wound support, (7-10 days) is required, but not for use in ligation, ophthalmic, cardiovascular and neurological procedures.	Same Intended Use
Suture Material	Composed of glycolide polymer	Vicryl Rapide composed of copolymer of glycolide and L-lactide
Suture Characteristics	Sorb-FAST® retains approximately 50% of its original tensile strength at one week post implantation. Absorbtion of the suture complete in 42 days.	Same
Sterilization Method	Ethylene Oxide gas	Same
Suture Diameter, Suture length, knot pull tensile, Strength and needle attachment strength	Meets or exceeds the performance requirements for " Absorbable Surgical Suture" as defined in USP 26 monographs. Pharmacopeia (USP) 26	Meet USP requirements
Packaging	Dry packaged in Aluminum Foil and polyester tear open	Same or equivalent manner

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Non-clinical testing was conducted on the subject devices to prove conformance to the requirements of USP standards to demonstrate substantial equivalence to the predicate device. Physical properties and functionality testing assured the safety and effectiveness of the subject device within its intended uses.

Results of the non-clinical testing demonstrate conformance with the USP standards and requirements for Absorbable surgical suture.

8. **Discussion of Clinical Tests Performed:**

No clinical trials were conducted.

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9. Conclusions:

Based on the technological characteristics and physical properties of the polyglycolic acid sutures , the description, the intended use of the device and conformance with the following performance standards like:

USP 26

ISO 9002 AND EN 46002

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

APR 2 9 2004

Internacional Farmaceutica S.A. de C.V.
c/o Ms. Carolann Kotula
MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K040282
Trade/Device Name: Atramat and SuperSorb Polyglycolic Acid Sutures
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable polyglycolic surgical suture
Regulatory Class: II
Product Code: GAM
Dated: February 5, 2004
Received: February 6, 2004

Dear Ms. Kotula:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit 1

510(k) Number (if known): K040282

Device Name: Atramat and SuperSorb Polyglycolic Acid Sutures

Indications For Use:

Atramat ® Polyglycolic Acid Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

sorb-FAST ® Polyglycolic Acid Sutures are indicated only for use in superficial general soft tissue approximation of the skin and mucosa, where only short term wound support (7-10 days) is required, but not for use in ligation, ophthalmic, cardiovascular and neurological procedures.

Prescription Use __X___ **(Per 21 CFR 801.109)** OR **Over-The Counter Use**_____ **(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)

Miriam C Provost

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

510(k) Number K040282