K060471
1/4

III. 510(K) Summary of Data and Information

JUL 26 2006

The following information is provided as required by 21 CFR § 807.87 for FSSB Chirurgische Nadeln GmbH's 510(k) premarket notification for FSSB Nylon Surgical Sutures and in accordance with FDA's "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" (June 3, 2003).

A. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

FSSB Nylon Surgical Sutures

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the FSSB Nylon Surgical Sutures is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices currently having 510k clearance.

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

FSSB Chirurgische Nadeln GmbH	Phone:	+49 7745 92 79 90
Allmendweg 2 (Postfach 1132)	Fax:	+49 7745 92 79 999
Jestetten, Germany D-79798		
US Contact:		
M Squared Associates, Inc.	Phone:	202-546-1262 ext. 257
Cherita James	Fax:	202-546-3848
719 A Street, NE	e-mail:	CJames@msquaredassociates.com
Washington DC 20002		
Date prepared: February 22, 2006		

Proprietary Name:	FSSB Nylon Surgical Sutures
Common Name:	Nonabsorbable Nylon Surgical Suture
Classification Status:	Class II per regulations §878.5020
Product Code:	GAR- Surgical, Nonabsorbable, Synthetic, Polyamide

Device Description

FSSB Nylon Surgical Suture is a monofilament non-absorbable sterile surgical suture composed of the long chain aliphatic polymers Nylon 6 Nylon 6,6. The suture is provided dyed (black). The pigment for the black dyed suture is Hematein black (Logwood: Color Code 75290). All products meet the requirements of 21 CFR 70.5(c) regarding the use of color additives in sutures.

The product is available in several lengths and USP diameters. The FSSB Surgical Suture is equipped with single or double high-grade stainless steel needles of various types of points, lengths, diameters and curves (Product List provided as Appendix A). The product meets all requirements established by the United States Pharmacopeia (U.S.P.) for nonabsorbable surgical sutures.

Intended Use

FSSB Nylon Surgical Suture (Non-absorbable Polyamide) is indicated for use in general soft tissue approximation and/or ligation including use in ophthalmic and neurological procedures.

Technological characteristics, comparison to predicate device.

	Predicate Devices			Subject Device
Company	**T.CAD**	**Sherwood-Davis & Geck**	**S & T**	**FSSB**
Device	International – Nylon	Surgilon®, Ophtalon® and Dermalon® Non-absorbable Surgical Suture	Micro surgical suture	FSSB Nylon Surgical Suture
510(k) Number	**K993998**	**K981582**	**K031531**	**No number yet**
Characteristic				
Intended use	General soft tissue approximation and/or ligation Including use in cardiovascular ophthalmic and neurological procedures.	General soft tissue approximation and/or ligation Including use in cardiovascular ophthalmic and neural tissue.	General soft tissue approximation and/or ligation Including use in cardiovascular and ophthalmic l procedures.	General soft tissue approximation and/or ligation including use in ophthalmic and neurological procedures.
Suture Material	Nylon 6 or Nylon 6,6	Nylon 6 or Nylon 6,6	Nylon 6 or Nylon 6,6	Nylon 6 or Nylon 6,6
Suture Characteristics	Not absorbed, progressive degradation of the Nylon in vivo may result in gradual loss of all of the suture's tensile strength over time	Not absorbed, progressive hydrolysis of the Nylon in vivo may result in gradual loss of all of the suture's tensile strength over time	Unknown	Not absorbed, progressive hydrolysis of the Nylon in vivo may result in gradual loss of all of the suture's tensile strength over time
Suture Diameter	Meet U.S.P. Requirements	Unknown	Unknown	U.S.P. 28 for diameter 861
How supplied	Monofilament thread, coated or uncoated, undyed or dyed with an FDA listed color additive. Sterile and offered for Single Use Only. Available with or without surgical needle.	Braided and monofilament sutures available in various lengths and diameters with or without surgical needles.	Monofilament, dyed black available in various lengths and diameters with surgical needles.	Monofil, dyed, variety of lengths and diameters with surgical needle.
Packaging	Dry packaged in Aluminum Foil and Polyester tear open packaging	Tyvek/Mylar packaging	Unknown	Double packaged Heat sealed

Technological Characteristics and Substantial Equivalence

The FSSB Nylon Surgical Sutures and the identified predicate devices have the same indications for use, are made from the same materials (Nylon 6 or Nylon 6,6), and have similar design features (monofilament, dyed, nonabsorbable, various lengths, available with needle). Performance testing has demonstrated that any minor differences between the FSSB Nylon Surgical Sutures and the predicate devices do not raise new questions of device safety or effectiveness.

Discussion of performance testing.

A collection of tests has been conducted to characterize biocompatibility, diameter, tensile strength, and properties such as pliability and handling in accordance to:

- ISO 10993 standards
- USP 28 <861>, <871>, <881>
- Class II Special Control Guidance, Surgical Suture; Guidance for Industry and FDA, June 3, 2003

Conclusion

FSSB Nylon Surgical Suture has the same principles of operation and similar technological characteristics as the previously 510k cleared predicates. The minor differences do not present new issues of safety or effectiveness.

Based on extensive performance testing and a comparison to the predicate devices, we believe that the FSSB Nylon Surgical Suture is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness. Additionally, the device has identical indications to the predicate devices and the labeling of the device is consistent both with FDA's guidance as well as current medical practice.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 2006

FSSB Chirurgische Nadeln GmbH
% M Squared Associate
Ms. Cherita James
719 A Street, Northeast
Washington, District of Columbia 20002

Re: K060471
Trade/Device Name: FSSB Nylon Surgical Suture
Regulation Number: 21 CFR 878.5020
Regulation Name: Nonabsorbable polyamide surgical suture
Regulatory Class: II
Product Code: GAR
Dated: July 20, 2006
Received: July 24, 2006

Dear Ms. James:

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,

Barbara Buchman

for

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

Enclosure

K060471

II. Premarket Notification Indications for Use Statement

510(k) Number:	To be assigned
Device Name:	FSSB Nylon Surgical Suture
Indications for Use:	**FSSB Nylon Surgical Suture** (Non-absorbable Polyamide) is indicated for use in general soft tissue approximation and/or ligation including use in ophthalmic and neurological procedures.

Prescription Use (Part 21 CFR 801 Subpart D)	X	Or	Over-the-Counter Use (Part 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 K060471