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DEC - 2 2003

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ABBREVIATED 510(k)
SUMMARY REPORT OF SAFETY AND EFFECTIVENESS
AND ADHERENCE TO THE *CLASS II SPECIAL CONTROLS GUIDANCE DOCUMENT: SURGICAL SUTURES* ISSUED ON JUNE 3, 2003

Device Name
The Stryker Mini-Mender Meniscal Repair System consists of a set of disposable pre-curved Cannulas and double-armed stainless steel needles pre-attached to USP non-absorbable, braided polyester surgical suture. The needles-suture are pre-assembled to a pair of disposable Introducers (needle-suture passers).

Classification Name:	Cannula, Surgical, General & Plastic Surgery
Device Classification:	21 CFR §878.4800, **Class I - Exempt**
Common and Usual Name:	Cannula (GEA)
Classification Name:	Passer, Wire, Orthopedic
Device Classification:	21 CFR §888.4540, **Class I - Exempt**
Common and Usual Name:	Passer (HXI)
Classification Name:	Non-Absorbable Poly(ethylene terephthalate) Surgical Sutures
Device Classification:	21 CFR §878.5000, **Class II**
Common and Usual Name:	Polyester Nonabsorbable Surgical Sutures (GAT)
Proprietary Name:	Stryker Mini-Mender Meniscal Repair System

Predicate Devices
Linvatec SharpShooter Meniscal Repair System, currently marketed by Linvatec/CONMED (Largo, FL).

Guidance Document
Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA issued on June 3, 2003

Summary
This summary of 510(k) safety and effectiveness is being submitted in accordance with requirements of SMDA 1990 and of the Special Controls as defined in section 513(a)(1)(B) of the Act for an Abbreviated 510(k).

The Stryker Mini-Mender Meniscal Repair System is intended to pass suture through soft tissue for suture fixation of meniscal tears. The use of suture to repair meniscus tears is common, considered the "Gold Standard" in meniscal repair, and has been well published in professional journals such as *Operative Techniques in Orthopaedics* and *The American Journal of Sports Medicine* (See Tab 1)

The Stryker Mini-Mender Meniscal Repair System consists of a set of disposable pre-curved Cannulas and double-armed stainless steel needles pre-attached to USP non-absorbable, braided polyester surgical suture. The needles-suture are pre-assembled to a pair of disposable Introducers (needle-suture passers).

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Stryker will acquire suture from a suture manufacturer that has received FDA clearance for the suture, such as Genzyme Biosurgery/Teleflex Medical (510(k) #K021019), with an intended use as specified for the Mini-Mender Meniscal Repair System. Stryker will assemble the suture to the Introducer and sterilize (reprocess) the device/suture prior to market release.

The Stryker Mini-Mender Meniscal Repair System will be provided pre-assembled, sterile for single-use applications (ASTM 4169). The device will be sterilized by Gamma irradiation (EN 552) and validated to a sterility assurance level (SAL) of 10^{-6}. The device is biocompatible per ISO-10993 and G95-1. The Stryker Mini-Mender Meniscal Repair System is substantially equivalent in intended use, safety, and efficacy to the predicate device and conforms to USP Section XXV – Nonabsorbable Surgical Sutures and the *Class II Special Controls Guidance Document: Surgical Sutures* issued on June 3, 2003.

The Stryker Mini-Mender Meniscal Repair System is considered substantially equivalent to the Linvatec SharpShooter Meniscal Repair System.

Contact: MMS

Date: Aug. 29, 2003

Melissa Murphy
Regulatory Representative
Stryker Endoscopy
5900 Optical Court
San Jose, CA 95138
(408) 754-2000 x.2148

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 2 2003

Ms. Melissa Murphy
Regulatory Representative
Stryker Endoscopy
5900 Optical Court
San Jose, California 95138

Re: K032901
Trade/Device Name: Stryker Mini-Mender Meniscal Repair System
Regulation Number: 21 CFR 878.5000, 21 CFR 888.4540
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture, Orthopedic manual surgical instrument
Regulatory Class: II, I
Product Code: GAT, LXH
Dated: August 20, 2003
Received: September 17, 2003

Dear Ms. Murphy:

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

K032901

August 20, 2003

510(k) Number if known:_____

INDICATION FOR USE:

The Stryker Mini-Mender Meniscal Repair System is intended for use in arthroscopic suture fixation techniques of meniscal tears.

The Stryker Mini-Mender Meniscal Repair System is intended for single-use only.

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 K032901

Prescription Use ✓ OR Over-the-Counter Use _____

(Per 21 CFR 801.109)