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510(k) Summary of Safety and Effectiveness

SUBMITTER: Surgical Devices, a global business unit of Tyco Healthcare Group LP (d/b/a Covidien)
60 Middletown Avenue
North Haven, CT 06473
Tel. No.: (203) 845-1000

DEC 01 2008

CONTACT PERSON: Tim M. Lohnes
Manager, Regulatory Affairs

DATE PREPARED: August 27, 2008

TRADE/PROPRIETARY NAME: Covidien Sport Surgery AS Meniscal Repair Device

PREDICATE DEVICE(S):

Classification Name:	Nonabsorbable poly(ethylene terephthalate) surgical suture
Device Classification:	CFR 878.5000 (GAT) Class II
Common and Usual Name:	Polyester Nonabsorbable Surgical Sutures (GAT)
Proprietary Name:	TiCron™ surgical suture
510(k) Submitter/Holder:	Surgical Devices, a global business unit of Tyco Healthcare Group LP (d/b/a Covidien)
510(k):	K930591

Classification Name:	Suture Retention Device/Synthetic Nonabsorbable Polyethylene Suture
Device Classification:	21 CFR 878.5000 (GAT) Class II
Common and Usual Name:	Meniscal Repair Device
Proprietary Name:	Smith & Nephew Ultra Fast-Fix Meniscal Repair System
510(k) Submitter/Holder:	Smith & Nephew, Inc. Endoscopy Div.
510(k) no.:	K072322

Classification Name:	Nonabsorbable poly(ethylene terephthalate) surgical suture
Device Classification:	CFR 878.5000 (GAT) Class II, 21 CFR 888.4540 (LXH) Class I
Common and Usual Name:	Polyester Nonabsorbable Surgical Sutures, Orthopedic manual surgical instrument
Proprietary Name:	Stryker Mini-Mender Meniscal Repair System
510(k) Submitter/Holder:	Stryker Endoscopy
510(k) no.:	K032901

DEVICE DESCRIPTION: The Covidien Sports Surgery AS Meniscal Repair Device is a sterile single use device for the approximation of soft tissue such as for the repair of meniscal tears. The disposable single use Device is comprised of a suture-passing needle mechanism which is pre-loaded with a strand of Size 2/0 nonabsorbable polyethylene terephthalate surgical suture (TiCron™) which includes a pre-tied knot.

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INTENDED USE	The Covidien Sports Surgery AS Meniscal Repair Device is intended to be used to approximate soft tissue such as during the repair of meniscal tear injuries.
TECHNOLOGICAL CHARACTERISTICS	The Covidien Sports Surgery AS Meniscal Repair Device is substantially equivalent to the predicate devices with regard to passing suture in order to deliver a pre-tied knot for the repair of meniscal tear injuries.
MATERIALS:	All components of the Covidien Sports Surgery AS Meniscal Repair Device are comprised of materials which are in accordance with ISO Standard 10993-1.
PERFORMANCE DATA:	Performance testing was conducted to verify that the Meniscal Repair Device is safe and effective and performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Surgical Devices
% Mr. Tim M. Lohnes
Manager, Regulatory Affairs
60 Middleton Avenue
North Haven, Connecticuit 06473

DEC 0 1 2008

Re: K082535
Trade/Device Name: Covidien Sports Surgery AS Meniscal Repair Device
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT
Dated: August 27, 2008
Received: September 2, 2008

Dear Mr. Lohnes:

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

K082535

Indications For Use

510(k) Number (if known): _____

Device Name: Covidien Sports Surgery AS Meniscal Repair Device

Indications For Use:

"The Covidien Sports Surgery AS Meniscal Repair Device is intended for use for approximation of soft tissue such as the repair of meniscal tear injuries"

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Neil R. P. Ogden for mpm

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

510(k) Number K082535