K091016

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
	MAY - 4 2009
CONTACT PERSON:	Tim M. Lohnes, Manager, Regulatory Affairs
DATE PREPARED:	April 7, 2009
TRADE/PROPRIETARY NAME:	Covidien Sport Surgery AS Meniscal Repair Device with High Strength Suture
PREDICATE DEVICE(S):	Covidien Sport Surgery AS Meniscal Repair Device
DEVICE DESCRIPTION:	The Covidien Sports Surgery AS Meniscal Repair Device with High Strength Suture is a sterile single use device for the approximation of soft tissue such as the repair of meniscal tears. The disposable single use Device is comprised of a suture-passing needle mechanism which is pre-loaded with Size 2/0 Force Fiber Ultra High Molecular Weight (UHMW) Non Absorbable Polyethylene suture (K040472), inclusive of a pre-tied knot. The distal end of the device will be offered in various angular configurations to enable access to areas of the meniscal anatomy, and to allow for user preference.
INTENDED USE	The Covidien Sports Surgery AS Meniscal Repair Device with High Strength Suture 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 with High Strength Suture is substantially equivalent to the predicate device 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 with High Strength Suture are comprised of materials which are evaluated in accordance with ISO Standard 10993-1.
PERFORMANCE DATA:	Performance testing was conducted to verify that the Meniscal Repair Device with High Strength Suture 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

MAY - 4 2009

Covidien
% Mr. Tim M. Lohnes
Manager, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K091016
Trade/Device Name: Covidien Sports Surgery All Suture (AS) Meniscal Repair Device with High Strength Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT
Dated: April 8, 2009
Received: April 9, 2009

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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 for
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K091016

Device Name:

Covidien Sports Surgery All Suture (AS) Meniscal Repair Device with High Strength Suture

Indications For Use:

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

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

David Krause for MKM

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

510(k) Number K091016