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SECTION IV

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

FAST-FIX 360 Meniscal Repair System

Date Prepared: 24 NOV 2009

JAN 2 8 2010

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road

Andover, MA 01810

B. Company Contact

Julie Acker, RAC

Senior Regulatory Affairs Specialist

Phone: (508) 261-3618

FAX: (508) 261-3620

C. Device Name

Trade Name:	FAST-FIX 360 Meniscal Repair System
Common Name:	Suture Retention Device
Classification Name:	Suture Retention Device/Synthetic Nonabsorbable Polyethylene Suture
Product Code:	GAT
Regulation Number:	21 CFR §878.5000
Device Class	II
Panel	General & Plastic Surgery

D. Predicate Devices

The Smith & Nephew FAST-FIX 360 Meniscal Repair Systems is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution: Smith & Nephew FAST-FIX Meniscal Repair System (K002261) and Ethicon PDS Suture (N18331)

E. Description of Device

The Smith & Nephew FAST-FIX 360 Meniscal Repair System is an all-inside meniscal repair device. Each device includes two non-absorbable polymer implants, pre-tied with #2-0 non-absorbable suture and pre-loaded into a needle delivery system. The FAST-FIX 360 Meniscal Repair System is provided sterile for single use only.

F. Intended Use

The Smith & Nephew FAST-FIX 360 Meniscal Repair System is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures such as shoulder stabilization (Bankart Repair), rotator cuff repair, meniscal repair and gastrostomy.

G. Comparison of Technological Characteristics

The Smith & Nephew FAST-FIX 360 Meniscal Repair System is substantially equivalent in design, intended use and fundamental scientific technology to the predicate devices defined in this submission. The proposed devices have been demonstrated to be substantially equivalent and raise no new issues of safety and efficacy.

H. Summary Performance Data

Cyclic load and ultimate tensile strength performance testing demonstrate that the fixation properties of the Smith & Nephew FAST-FIX 360 Meniscal Repair System are substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
% Ms. Julie Acker, RAC
Senior Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

JAN 28 2010

Re: K092508
Trade/Device Name: FAST-FIX 360 Meniscal Repair System
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT
Dated: November 24, 2009
Received: November 27, 2009

Dear Ms. Acker:

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 note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

K092508

Indications for Use

510(k) Number (if known): _____

Device Name: FAST-FIX 360 Meniscal Repair System

Indications for Use:

The Smith & Nephew FAST-FIX 360 Meniscal Repair System is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures such as shoulder stabilization (Bankart Repair), rotator cuff repair, meniscal repair and gastrostomy.

Prescription Use ___x_____ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 807 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 MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092508