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K093943

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.

Smith & Nephew BIOSURE™ SYNC Tibial Fixation Device

Date Prepared: December 21, 2009

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810

B. Company Contact

Julie Acker, RAC
Sr. Regulatory Affairs Specialist
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C. Device Name

Trade Name:	BIOSURE SYNC Tibial Fixation Device
Common Name:	Screw, Fixation, Bone
Classification Name:	Smooth or threaded metallic bone fixation fastener per 21 CFR §888.3040

D. Predicate Devices

The Smith & Nephew BIOSURE SYNC Tibial Fixation Device is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed devices in commercial distribution: Smith & Nephew BIOSURE® PK Screw (K083635), Smith & Nephew GTS Sleeve (K040542) and the DePuy Mitek Intrafix (K983560).

E. Description of Device

The Smith & Nephew BIOSURE SYNC Tibial Fixation Device is an intra-tunnel device used to secure soft tissue grafts to bone during cruciate ligament reconstruction procedures. The fixation device is a polymer implant for use with BIOSURE PK Screws (25 mm length). The device is provided sterile, for single use only.

F. Intended Use

The Smith & Nephew BIOSURE SYNC Tibial Fixation Device is indicated for use in combination with BIOSURE PK Screws for fixation of soft tissue to bone during cruciate ligament reconstruction.

G. Comparison of Technological Characteristics

The proposed Smith & Nephew BIOSURE SYNC Tibial Fixation Device and the predicate devices have the same intended use and basic fundamental scientific technology. The proposed device and the predicate devices are intended to fixate soft tissue grafts to bone by intra-tunnel compression of the graft. The proposed and predicate devices are manufactured of non-absorbable material, and performance testing demonstrates that the proposed devices are as safe and as effective as currently marketed predicate devices.

H. Summary Performance Data

Performance testing demonstrates that the insertion and fixation properties of the Smith & Nephew BIOSURE SYNC Tibial Fixation Device are substantially equivalent to the predicate devices. Based on the indications for use, the technological characteristics, and comparison to predicate devices, the BIOSURE SYNC Tibial Fixation Device has been demonstrated to be substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

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

MAR - 5 2010

Re: K093943
Trade/Device Name: BIOSURE SYNC Tibial Fixation Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC, MBI
Dated: December 21, 2009
Received: December 22, 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

Indications for Use

510(k) Number (if known): K093943

Device Name: BIOSURE SYNC Tibial Fixation Device

Indications for Use:

The Smith & Nephew BIOSURE SYNC Tibial Fixation Device is indicated for use in combination with BIOSURE PK Screws for fixation of soft tissue to bone during cruciate ligament reconstruction.

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)

for MXn

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

510(k) Number K093943