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SECTION V
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 ENDOBUTTON DIRECT

Date Prepared: January 5, 2011

A. Submitter's Name:

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

B. Company Contact

Deana Boushell
Principle Regulatory Affairs Specialist
Phone: (508) 337-4036
FAX: (508) 261-3620

C. Device Name

Trade Name:	Smith & Nephew ENDOBUTTON Direct
Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue
Regulation Name:	Single/multiple component metallic bone fixation appliances and accessories
Regulation Number:	21 CFR 888.3030
Product Code:	MAI

D. Predicate Devices

The Smith & Nephew ENDOBUTTON DIRECT is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution: The Smith & Nephew Endobutton CL (K980155).

E. Description of Device

The ENDOBUTTON DIRECT is a machined titanium implant designed to provide cortical fixation in the repair of tendons and ligaments. The design of the ENDOBUTTON DIRECT allows for the device to be endoscopically delivered from a single access point. The harvested graft is looped through the closed portion of the ENDOBUTTON DIRECT and by pulling on a lead suture attached to the top of the ENDOBUTTON DIRECT the construct is moved through the tunnel. The trailing suture located distal to the graft is then used to flip the device into position, lying flat across the tunnel opening on top of the femoral cortex.

F. Intended Use

The Smith & Nephew ENDOBUTTON DIRECT is used for fixation of tendons and ligaments during orthopedic reconstruction procedures such as Anterior Cruciate Ligament (ACL).

G. Comparison of Technological Characteristics

The Smith & Nephew ENDOBUTTON DIRECT is substantially equivalent in design, materials, function and intended use to the Smith & Nephew Endobutton CL, cleared in K980155. The proposed and the predicate devices both have the same intended use, button material and are offered in a range of sizes.

H. Summary Performance Data

The performance testing conducted demonstrates substantial equivalence to the Smith & Nephew Endobutton CL, cleared in K980155. The bench top testing included tensile testing and demonstrates that the differences in the new device and the predicate device do not raise any new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew Inc.
c/o Ms. Deana Boushell
Principal Regulatory Specialist
150 Minuteman Road
Andover, Massachusetts 01810

JAN - 5 2011

Re: K102982
Trade/Device Name: Smith & Nephew ENDOBUTTON DIRECT
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI
Dated: October 6, 2010
Received: October 7, 2010

Dear Ms. Boushell:

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 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.

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): K102982

Device Name: Smith & Nephew ENDOBUTTON DIRECT

JAN - 5 2011

Indications For Use:

The Smith & Nephew ENDOBUTTON DIRECT Fixation Device is used for fixation of tendons and ligaments during orthopedic reconstruction procedures such as Anterior Cruciate Ligament (ACL).

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 M. Melkerson

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

510(k) Number K102982