SECTION IV APR 23 2008

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.

PLLA/HA Screw

Date Prepared: February 8, 2008

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road

Andover, MA 01810

B. Company Contact

Deana Boushell

Principal Regulatory Specialist

T 508 337 4036

F 508 261 3620

C. Device Name

Trade Name:	PLLA/HA Screw
Common Name:	Screw, Fixation, Bone
Classification Name:	Smooth or threaded metallic bone fixation fastener

D. Predicate Devices

The Smith & Nephew PLLA/HA Screw is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution:

- HAPLA Interference Screw K002274
- PLC Screw K051310

E. Description of Device

The Smith & Nephew PLLA/HA Screw is an tapered interference screw for fixation of bone-tendon-bone or soft tissue grafts during anterior or posterior cruciate ligament reconstruction surgery.

F. Intended Use

The Smith & Nephew PLLA/HA Screw is indicated for fixation of bone-tendon-bone or soft tissue grafts during Anterior and/or Posterior Cruciate Ligament (ACL/PCL) reconstruction.

G. Comparison of Technological Characteristics

The Smith & Nephew PLLA/HA Screw is essentially identical to the HAPLA Interference Screw and the PLC Screw described in K002274 and K051310 respectively. The PLLA/HA Screw is a cannulated, sterile, single use bone screw, made of polylactic acid, a resorbable polymer, and hydroxylapatite, an inorganic ceramic.

H. Summary Performance Data

Results of product validation testing demonstrates substantial equivalence to the predicate devices; HAPLA Interference Screw (K002274) and the PLC Screw (K051310).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 2008

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

Re: K080358
Trade/Device Name: PLLA/HA Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: February 8, 2008
Received: February 11, 2008

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.

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) 276-0120. 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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
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): K080358

Device Name: PLLA/HA Screw

Indications for Use:

The Smith & Nephew PLLA/HA Screw is indicated for fixation of bone-tendon-bone or soft tissue grafts during Anterior and/or Posterior Cruciate Ligament (ACL/PCL) reconstruction.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___No___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden

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

510(k) Number K080358