APR 1 4 2004

K040331
page 1 of 2

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 Titanium Interference Screws

Date Prepared: February 6, 2004

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

130 Forbes Blvd., Mansfield, MA 02048

B. Company Contact

Denise Lima

Regulatory Affairs Specialist

Ph: (508)337-4036 Fax: (508)261-3620

C. Device Name

Trade Name:	Smith & Nephew Titanium Interference Screws
Common Name:	Screw, Fixation, Bone
Classification Name:	Smooth or threaded metallic bone fixation fastener

D. Predicate Devices

The Smith & Nephew Titanium Interference Screws are substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed devices in commercial distribution: K895711 and K900132, Acufex Interference Screws; K932027, Oregon (Dyonics) Fixation System; K921481, Cannuflex Interference Screws.

K040331
page 2 of 2

E. Description of Device

The Smith & Nephew Titanium Interference Screws are available in various geometric configurations. The Smith & Nephew Titanium Interference Screws are made with titanium alloy material. The range in diameters and lengths, combined with the variations in geometric configurations, provide the surgeon with a wide variety of sizes/configurations to choose from. Screws are available in both cannulated and non-cannulated styles. The screws may be purchased either sterile or non-sterile, to be sterilized by the end user.

F. Intended Use

The Smith & Nephew Interference Screws are used for fixation of ligaments and tendons in patients requiring ligament and tendon repair.

G. Comparison of Technological Characteristics

Although there are some dimensional variations between the Smith & Nephew Titanium Interference Screw and the predicate devices, there are no new issues raised concerning safety or efficacy of the device.

H. Summary Performance Data

Comparison of the results of the insertion torque testing and pullout force demonstrated that there were no statistically significant differences between the Smith & Nephew Titanium Interference Screw and the predicate devices.

Denise Lima 2/6/04

Denise Lima

Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 4 2004

Ms. Denise Lima
Regulatory Affairs Specialist II
Smith & Nephew, Inc.
Endoscopy Division
150 Minuteman Road
Andover, Massachusetts 01810

Re: K040331
Trade/Device Name: Smith & Nephew Titanium Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: February 10, 2004
Received: February 12, 2004

Dear Ms. Lima:

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.

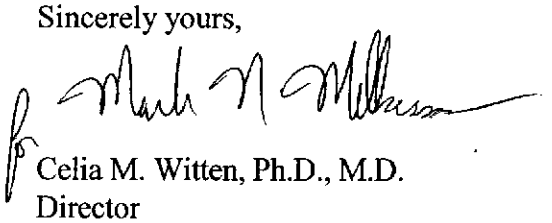
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
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): K040331

Device Name: Smith & Nephew Titanium Screws

Indications For Use:

The Smith & Nephew Interference Screws are used for fixation of ligaments and tendons in patients requiring ligament or tendon repair.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

for Mark A Milhous

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

510(k) Number K040331