K072675

OCT 15 2007

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 Arthroscope
Date Prepared:

A. Submitter's Name:

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

B. Company Contact

Janice Haselton
Sr. Regulatory Affairs Specialist
Phone: (978)749-1494
Fax: (978)749-1443

C. Device Name

Trade Name:	Smith & Nephew Arthroscope
Common Name:	Arthroscope
Classification Name:	Arthroscope

D. Predicate Devices

The current line of Smith & Nephew Arthroscopes serves as the predicate device for this submission (K043395).

E. Description of Device

Smith & Nephew Arthroscopes are reusable devices and are sterilized using a variety of sterilization methods. Arthroscopes are used by being inserted into an artificial opening of the human body to provide illumination and visualization of a joint space. The optical design of the standard arthroscope consists of the objective lens which creates the image and transfers it through the optical train by means of identical relays that maintain the image quality with very little degradation.

F. Intended Use

The Smith & Nephew line of rigid Arthroscopes/ENT Endoscopes is indicated to provide illumination and visualization in diagnostic and operative arthroscopic procedures, endoscopic examination and treatment of the nasal cavities and nasal pharynx.

In addition, the Smith & Nephew 4 mm diameter rigid Arthroscopes/ENT Endoscopes are indicated to provide illumination and visualization in the removal of loose bodies and soft tissue within the hip joint as size/length appropriate.

G. Comparison of Technological Characteristics

The Smith & Nephew Arthroscopes have the same Indications for Use as the predicate device, utilizes the same operating principle, incorporates the same basic design, and are manufactured under a Quality System.

H. Summary Performance Data

All verification data demonstrates that the device is safe and effective and performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2007

Smith & Nephew, Inc.
% Ms. Janice Haselton
Sr. Regulatory Affairs Specialist
Endoscopy Division
150 Minuteman Road
Andover, Massachusetts 01810

Re: K072675
Trade/Device Name: Smith & Nephew Arthroscope
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: September 20, 2007
Received: September 21, 2007

Dear Ms. Haselton:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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): K072675

Device Name: Smith & Nephew Arthroscope

Indications For Use: The line of rigid Arthroscopes/ENT Endoscopes is indicated to provide illumination and visualization in:
Diagnostic and operative arthroscopic procedures.
Endoscopic examination and treatment of the nasal cavities and nasal pharynx.

In addition, the Smith & Nephew 4 mm diameter rigid Arthroscopes/ENT Endoscopes are indicated to provide illumination and visualization in:
The removal of loose bodies and soft tissue within the hip joint as size/length appropriate.

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)

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

510(k) Number K072675