JAN 12 2005

K 043395

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 VideoArthroscope
Date Prepared: December 7, 2004

A. Submitter's Name:

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

B. Company Contact

Kathleen Burns
Regulatory Affairs Associate
Phone: (978)474-6301
Fax: (978)749-1443

C. Device Name

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

D. Predicate Devices

The current Smith & Nephew VideoArthroscope serves as the predicate device for this submission (K971253).

E. Description of Device

The Smith & Nephew VideoArthroscope is a reusable VideoArthroscope. The proposed device is available in a variety if diameters, lengths, and with direction of view ranging from 0° to 110° and incorporates a mechanical focus mechanism.

F. Intended Use

The Smith & Nephew line of rigid Multimode VideoArthroscopes/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 4.0mm diameter rigid VideoAthroscopes/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 VideoArthroscope has the same Indications for Use as the predicate device, utilizes the same operating principle, incorporates the same basic design, and is manufactured under a Quality System.

H. Summary Performance Data

All verification and validation 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

JAN 12 2005

Ms. Kathleen Burns
Regulatory Affairs Associate
Smith & Nephew, Inc.
150 Minuteman, Road
Andover, Massachusetts 01810

Re: K043395
Trade/Device Name: Smith & Nephew VideoArthroscope
Regulation Number: 21 CFR 888.1100, 21 CFR 874.4760
Regulation Name: Arthroscope, Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: II
Product Code: HRX, EOB
Dated: December 8, 2004
Received: December 10, 2004

Dear Ms. Burns:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost

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): K043395

Device Name: Smith & Nephew VideoArthroscope

Indications For Use: The Smith & Nephew VideoArthroscopes/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 VideoArthroscopes/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 K043395