Endoscopy Division
Smith & Nephew, Inc.
160 Dascomb Road, Andover, MA 01810 U.S.A.
Telephone: 508-749-1000
Telefax: 508-749-1599

Smith+Nephew K971253

June 13, 1997

510(k) Summary
Smith & Nephew, Inc., Endoscopy Division
Arthroscopes and Accessories

Substantial Equivalence :

The arthroscopes listed in this 510(k) are the same arthroscopes currently marketed by Smith & Nephew, Inc., Endoscopy Division. These arthroscopes are all considered size-appropriate for use within the hip joint as well as all other previously approved indications. Endoscopic Surgery Blades are similar to product currently marketed under 510(k) #K900070. Manual Instruments are longer versions of product currently marketed under 510(k) #K904284 or those that are Class I, exempt devices.

Predicate Device :

The devices in this 510(k) submission were originally reviewed and determined to be substantially equivalent to a predicate device under one or more of the following 510(k)s : #K771218, #K820367, #K880150, #K914559, #K961228, #K954989, #K904284, #K953695, #K941036, #K934299, #K912453, #K833587, and #K900070.

Summary of Device Function :

The Smith & Nephew, Inc., Endoscopy Division Arthroscopes and Accessories are to be used for illumination and visualization of joint spaces during arthroscopic procedures. Sterile, disposable Endoscopic Surgery Blades consist of several concentric tubes and various tip designs. The blades are used to resect and remove tissue endoscopically. The inner blade is driven by a motor. Tissue is removed by suction through the inner diameter of the inner blade.

Intended Use of Device :

The Smith & Nephew, Inc., Endoscopy Division Arthroscopes and Accessories are indicated for use in diagnostic and operative arthroscopic procedures to provide illumination and visualization of the shoulder, knee, elbow, ankle, wrist and jaw, also to provide illumination and visualization during arthroscopic diagnostic procedures and removal of loose bodies and soft tissue within the hip joint as size/length appropriate.

The Smith & Nephew, Inc., Endoscopy Division sterile, disposable Endoscopic Surgery Blades as indicated for use during arthroscopic resection of soft and osseous tissue in various large and small articular cavities including the hip joint. Blades which are size-appropriate are indicated for use in the following joints : shoulder, knee, elbow, ankle, wrist, jaw and the hip joint.

Comparison of Technological Characteristics of Predicate Device :

The design and functions of each of the items listed in this 510(k) notification are similar to those listed in the previous 510(k)s.

Elizabeth A. Ryan
Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 1997

Ms. Elizabeth A. Ryan
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, Massachusetts 01810

Re: K971253
Trade Name: Arthroscopes & Accessories, Endoscopic Surgery Blades, Manual Instruments
Regulatory Class: II
Product Code: HRX
Dated: March 31, 1997
Received: April 3, 1997

Dear Ms. Ryan:

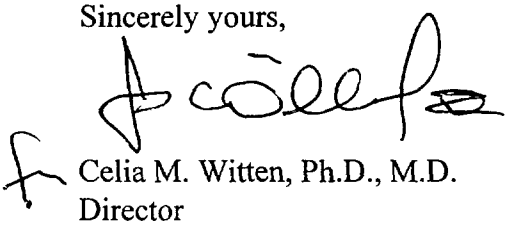
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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). You May, therefore, market the devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they May be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation May result in regulatory action. In addition, FDA May publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act May be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K971253

Device Name : Arthroscopes and Accessories, Sterile Disposable Endoscopic Surgery Blades, and Manual Instruments

Indications for Use :

The Smith & Nephew, Inc., Endoscopy Division Arthroscopes and Accessories are indicated for use in diagnostic and operative arthroscopic procedures to provide illumination and visualization of the shoulder, knee, elbow, ankle, wrist and jaw, also to provide illumination and visualization during arthroscopic diagnostic procedures and removal of loose bodies and soft tissue within the hip joint as size/length appropriate.

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(PLEASE DO 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 Devices
510(k) Number K971253

Prescription Use ✓ OR Over-the-Counter ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)