MAY 18 1998

Endoscopy Division
Smith & Nephew, Inc.
160 Dascomb Road, Andover, MA 01810 U.S.A.
Telephone: 978-749-1000
Telefax: 978-749-1599

Smith+Nephew

510(k) Summary
Smith & Nephew, Inc., Endoscopy Division
Dyonics Endoscopes

K980604

Substantial Equivalence:

The Smith & Nephew Dyonics Endoscopes are substantially equivalent in design, materials, function, and intended use to the line of Laparoscopes/Thoracoscopes offered by Karl Storz Endoscopy.

Predicate Device:

The predicate device for this submission is the line of Laparoscopes/Thoracoscopes offered Karl Storz Endoscopy Telescope for use in thoracic surgical procedures.

Summary of Device Function:

The Smith & Nephew Dyonics Endoscopes transfer light to the surgical site via glass fiber optics and allow visualization of the surgical site through a rod lens optical system. Selected endoscopes have working channels to accommodate surgeon preference.

Intended Use of Device:

Dyonics endoscopes are indicated for use in laparoscopic and thoracic surgical procedures to provide access, illumination and allow visualization or manipulation of body cavities, hollow organs and canals.

Comparison of Technological Characteristics of Predicate Device:

The basic technologies, design and function of the Smith & Nephew Dyonics line of endoscopes is substantially equivalent in materials, design and function to Laparoscopes/Thoracoscopes offered by Karl Storz Endoscopy. The minor differences in product specifications raise no new issues of safety and effectiveness.

Deborah J. Connors
Sr. Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 1998

Ms. Deborah Connors
Senior Regulatory Affairs Specialist
Smith & Nephew, Incorporated
160 Dascomb Road
Andover, Massachusetts 01810

Re: K980604
Trade Name: Smith & Nephew Dyonics Endoscopes and Accessories
Regulatory Class: II
Product Code: GCJ
Dated: February 13, 1998
Received: February 17, 1998

Dear Ms. Connors:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) 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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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 submission 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 legally marketed predicate devices 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,

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

Enclosures

510(k) Number : K980604

Device Name : Smith & Nephew, Inc., Endoscopy Division Dyonics Endoscopes

Indications for Use :

Dyonics endoscopes are indicated for use in laparoscopic and thoracic surgical procedures to provide access, illumination and allow visualization or manipulation of body cavities, hollow organs and canals.

(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 K980604

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

(Optional Format 1-2-96)