Endoscopy Division

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

DEC 11 1997

Smith+Nephew

510(k) Summary

Smith & Nephew, Inc., Endoscopy Division

Images Cystourethroscope and accessories

K972979

Substantial Equivalence:

The Smith & Nephew, Inc. Images Cystourethroscopes and accessories are substantially equivalent in design, materials, and intended use to Cystourethroscopes and accessories offered by Karl Storz Endoscopy.

Predicate Device:

The predicate device for this submission is the Karl Storz Endoscopy Cystourethroscopes and accessories.

Summary of Device Function:

The Images Cystourethroscopes and accessories transfer light to the surgical site via glass fiber optics and allow visualization of the surgical site through a series of optical lenses and prisms. Sheathes and obturators are offered to allow access to the surgical site.

Intended Use of Device:

Smith & Nephew Images Cystourethroscopes are indicated for use in the examination of the bladder, urethra and distal ureter, and using additional accessories, to perform various diagnostic and therapeutic procedures.

Smith & Nephew Semi-rigid and Flexible Manual Instruments are indicated for use in the endoscopic examination of the bladder, urethra and distal ureters and to perform various diagnostic and therapeutic procedures.

Comparison of Technological Characteristics of Predicate Device:

The basic design and function of the Images Cystourethroscopes and accessories is substantially equivalent to technologies, design and function of the Karl Storz Endoscopy Cystourethroscopes and accessories and present no new safety or effectiveness concerns.

Deborah J. Connors
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 1997

Ms. Deborah J. Connors
Regulatory Affairs Specialist
Endoscopy Division
Smith & Nephew, Inc.
160 Dascomb Road
Andover, Massachusetts 01810

Re: K972979
Smith & Nephew Images Cystourethroscopes and Accessories
Dated: October 30, 1997
Received: October 31, 1997
Regulatory class: II
21 CFR §876.1500/Product code: 78 FBO
21 CFR §876.4730/Product code: 78 KOA

Dear Ms. Connors:

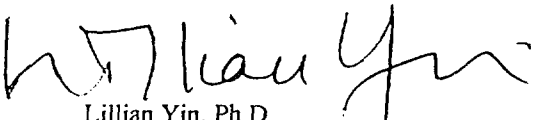
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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 (Premarket Approval), 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 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 device 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 device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, 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,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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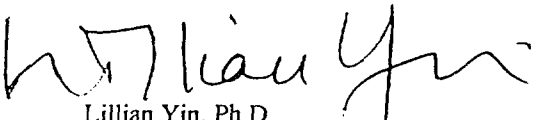

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
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Enclosure

K972979

510(k) Number : K 97 2979

Device Name : Smith & Nephew, Inc., Endoscopy Division Images Cystourethroscope and accessories

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Smith & Nephew Semi-rigid and Flexible Manual Instruments are indicated for use in the endoscopic examination of the bladder, urethra and distal ureters and to perform various diagnostic and therapeutic procedures.

(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D Ashley

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972979

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

(Optional Format 1-2-96)