K971188

JUN 27 1997

Endoscopy Division

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

510(k) Summary
Smith & Nephew, Inc., Endoscopy Division
Images Endoscopes and Accessories for Use in Hysteroscopic Surgical Procedures

Substantial Equivalence:

The Smith & Nephew, Inc. Images Endoscopes and accessories for use in hysteroscopic surgical procedures are substantially equivalent in design, materials, function, and intended use to telescopes and accessories offered by Karl Storz Endoscopy and hysteroscopes and accessories offered by Henke-Sass Wolf. Smith & Nephew Semi-rigid and Flexible Manual Instruments are substantially equivalent in design, materials, function, and intended use to hysteroscopic semi-rigid and flexible manual instruments offered by Circon ACMI and Richard Wolfe

Predicate Device:

The predicate devices for this submission are the Karl Storz Endoscopy Telescopes and accessories indicated for use in hysteroscopic surgical procedures, the Hysteroscopes and accessories offered by Henke-Sass Wolf and Semi-rigid and Flexible Manual Instruments offered by Circon ACMI and Richard Wolfe.

Summary of Device Function:

The Images Endoscopes 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. Hysteroscopic sheaths are used to access and maintain an opening into the uterus for introduction of the endoscope and surgical instruments. Sheaths also allow access for gas or liquid distention of the uterus. Semi-rigid and flexible manual instruments are utilized for examination and treatment of cervical and uterine tissues.

Intended Use of Device:

Smith & Nephew Images Endoscopes are used to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

Smith & Nephew Semi-rigid and Flexible Manual Instruments are indicated for endoscopic examination and treatment of the cervical canal and uterine cavity.

Comparison of Technological Characteristics of Predicate Device:

The basic technologies, design and function of the Smith & Nephew Semi-rigid and Flexible Manual Instruments and Images Endoscopes and accessories is substantially equivalent in materials, design and function to the Circon ACMI and Richard Wolfe Semi-rigid and Flexible Manual Instruments, the Karl Storz Endoscopy Telescopes and accessories for use in hysteroscopic procedures and to Henke-Sass Wolf Hysteroscopes and accessories. These devices present no new safety or effectiveness concerns.

Elizabeth A. Ryan
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 1997

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

Re: K971188
Images Hysteroscopes and Accessories
Dated: March 28, 1997
Received: March 31, 1997
Regulatory class: II
21 CFR §884.1690/Product code: 85 HIH

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

510(k) Number : K971188

Device Name : Smith & Nephew Images Hysteroscopes and accessories

Indications for Use :

Smith & Nephew Images Hysteroscopes and accessories are used to permit viewing of the cervial canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

Smith & Nephew Semi-rigid and Flexible Manual Instruments are indicated for endoscopic examination and treatment of the cerivcal canal and uterine cavity.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter R Salling
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971188

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

(Optional Format 1-2-96)