K982149

SEP 10 1998

510(k) Summary
Smith & Nephew, Inc., Endoscopy Division
Dyonics 2.7mm Microlaparoscope

Substantial Equivalence:

The Smith & Nephew Dyonics 2.7mm Microlaparoscope is substantially equivalent in design, materials, function, and intended use to the Richard Wolf Medical 2.0mm mini laparoscope.

Predicate Device:

The predicate device for this submission is the Richard Wolf Medical 2.0mm mini laparoscope.

Summary of Device Function:

The Smith & Nephew Dyonics 2.7mm Microlaparoscope transfers light to the surgical site via glass fiber optics and allows visualization of the surgical site through a rigid rod-lens optical design.

Intended Use of Device:

The Dyonics 2.7mm Microlaparoscope is indicated for use in general laparoscopy and gynecological laparoscopy to provide access, illumination and allow visualization or manipulation of body cavities, hollow organs and canals during diagnostic and operative surgical procedures.

For use in gynecological laparoscopy the following specific indications apply:

- Unexplained pelvic pain (acute, chronic)
- Infertility work-up
- Tubal sterilization
- Diagnosis and/or treatment of ectopic pregnancy
- Evaluation, diagnosis and/or treatment of pelvic tumors, including myoma (less than 16 weeks gestational size)
- Evaluation of congenital anomalies of the pelvic organs
- Retrieval of foreign bodies
- Determination of the presence and extent of pelvic endometriosis
- Determination of the presence and extent of pelvic inflammatory disease (if not in acute stage)
- Access to abdomen for surgical procedures such as LAVH
- Visualization, diagnosis and/or treatment of perforated abdominal (pelvic) organs

Comparison of Technological Characteristics of Predicate Device:

The basic technologies, design and function of the Smith & Nephew Dyonics 2.7mm Microlaparoscope is substantially equivalent in materials, design and function to the Richard Wolf Medical 2.0mm mini laparoscope.

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

SEP 10 1998

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

Re: K982149
Dyonics 2.7mm Microlaparoscope
Dated: August 27, 1998
Received: August 28, 1998
Regulatory Class: II
21 CFR 884.1720/Procode: 85 HET

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 requirements, 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/dsma/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 : K982149

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

Indications for Use :

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982149

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

(Optional Format 1-2-96)

For use in gynecological laparoscopy the following specific indications apply: (cont'd)

- Evaluation of congenital anomalies of the pelvic organs
- Retrieval of foreign bodies
- Determination of the presence and extent of pelvic endometriosis
- Determination of the presence and extent of pelvic inflammatory disease (if not in acute stage)
- Access to abdomen for surgical procedures such as LAVH
- Visualization, diagnosis and/or treatment of perforated abdominal (pelvic) organs