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JAN 17 2002

510(k) Summary
Smith & Nephew Operative Hysteroscope and Accessories
Date Prepared:

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, MA 01810

B. Company Contact

Janice Haselton
Regulatory Affairs Specialist

C. Device Name

Trade Name:	Smith & Nephew Operative Hysteroscope and Accessories
Common Name:	Hysteroscope
Classification Name:	Hysteroscopes and Accessories

D. Predicate Devices

Smith & Nephew's Images Hysteroscopes and Accessories K 971188
Richard Wolf's Hysteroscopes Operating Sheath and Insert K 000673

E. Description of Device

The proposed Smith & Nephew Operative Hysteroscope and Accessories is a reusable surgical device that incorporates a working channel into the needle portion of the hysteroscope. A reusable continuous flow sheath and blunt obturator are offered for atraumatic insertion through the uterine cervix.
The needle portion of the hysteroscope has an oval configuration to accommodate adequate fluid flow between the sheath and hysteroscope. The working channel is D-shaped to accommodate the fiber bundles and optical train in the needle.
The Smith & Nephew Operative Hysteroscope is compatible with the ETO and autoclave sterilization process. The device accessories can be autoclaved for reuse.

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D. Intended Use

The Smith & Nephew Operative Hysteroscope and Accessories are used to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures

E. Comparison of Technological Characteristics

Smith & Nephew's Operative Hysteroscope and accessories is substantially equivalent in design, materials of construction, function and intended use to the Smith & Nephew Images Hysteroscopes and accessories and the Richard Wolf operative Hysteroscopes. The changes in geometry do not introduce any new risks to the proposed device.

Janice Haselton

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Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2002

Ms. Janice Haselton
Regulatory Affairs Specialist
Smith & Nephew, Inc.
160 Dascomb Road
ANDOVER MA 01810

Re: K013870
Trade/Device Name: Smith & Nephew Operative Hysteroscope and Accessories
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: 85 HIH
Dated: November 19, 2001
Received: November 21, 2001

Dear Ms. Haselton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

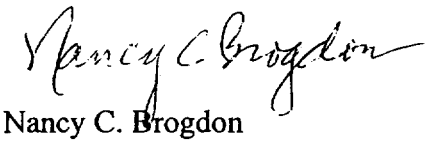
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number : K013870

Device Name : Smith & Nephew Operative Hysteroscope and Accessories

Indications for Use:

The Smith & Nephew Operative Hysteroscope and accessories are used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013870