K041774
Page 1 of 2

OCT 7 - 2004

**SECTION IV**

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION**

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

**Smith & Nephew IUR Reciprocating Morcellator**

Date Prepared: June 30, 2004

**A. Submitter's Name:**

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road

Andover, MA 01810

**B. Company Contact**

Janice Haselton

Regulatory Affairs Specialist

Phone: (978) 749-1494

Fax: (978) 749-1443

**C. Device Name**

Trade Name: Smith & Nephew IUR Reciprocating Morcellator

Common Name: Hysteroscopic Morcellator

Classification Name: Hysteroscopes and Accessories

**D. Predicate Devices**

The Smith & Nephew Smith & Nephew IUR Reciprocating Morcellator is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution Smith & Nephew IUR Morcellator cleared in K031787.

**E. Description of Device**

The IUR Reciprocating Morcellator is a disposable, sterile, reciprocating morcellator used in conjunction with the currently cleared Smith & Nephew IUR Morcellation

System (K031787), to remove submucous myomas and endometrial polyps from the uterus. The reciprocating design utilizes both a rotational and reciprocating cutting mechanisms. The predicate design utilizes a rotational cutting mechanism only.

## F. Intended Use

The Smith & Nephew IUR Morcellation System is intended for use in gynecological procedures by trained professional gynecologists to resect and remove endometrial tissue for the following indications, submucous myomas and endometrial polyps.

## G. Comparison of Technological Characteristics

Both the proposed IUR Reciprocating Morcellator and the predicate IUR Rotary Morcellator, cleared in K031787, are substantially equivalent in intended use, materials and overall design dimensions. Both devices snap and lock in place into the motor drive unit of the IUR Morcellation control unit, via a latch mechanism on the outer adapter body. Based on these similarities Smith & Nephew believes that the IUR Reciprocating Morcellator is substantially equivalent to the predicate device currently on the market.

## H. Summary Performance Data

In vitro testing of the IUR Reciprocating Morcellator demonstrates that the addition of new materials and the proposed design modifications does not impact the safety and performance of the proposed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2004

Ms. Janice Haselton
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Endoscopy Division
150 Minuteman Road
ANDOVER MA 01810

Re: K041774
Trade/Device Name: IUR Reciprocating Morcellator
Regulation Number: 21 CFR §884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: 85 HIH
Dated: September 10, 2004
Received: September 13, 2004

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 (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 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 Section 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:

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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

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

Enclosure

**Indications for Use**

510(k) Number (if known): K041774

Device Name: _Smith & Nephew IUR Reciprocating Morcellator _____

Indications For Use:

The Smith & Nephew IUR Morcellation System is intended for use in gynecological procedures by trained professional gynocologists to resect and remove endometrial tissue for the following indications, submucous myomas and endometrial polyps.

Prescription Use ___x_____ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041774