Endoscopy
[redacted]

We are **smith&nephew**

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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.

TRUCLEAR™ Incisor® Plus Blade 2.9

Date Prepared: November 17, 2010

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road, Andover, MA 01810

B. Company Contact

Janice Haselton

Sr. Regulatory Affairs Specialist

T 978-749-1494

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C. Device Name

Trade Name:	TRUCLEAR™ Incisor® Plus Blade 2.9
Common Name:	Hysteroscope and Accessories
Classification Name:	Hysteroscope and Accessories per CFR §884.1690

D. Predicate Devices

The TRUCLEAR™ Incisor® Plus Blade 2.9 is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution, Hysteroscopic Rotary Morcellator cleared in K031787.

Endoscopy
[redacted]

E. Description of Device

The TRUCLEAR™ Incisor® Plus Blade 2.9 consists of an inner and outer stainless steel tube. Both tubes have a molded hub on the proximal end and a cutting window with symmetrical teeth on the distal end. The inner tube fits into the outer tube and is snapped and locked in place into a motor drive unit, which rotates the inner tube of the device. Tissue is simultaneously shaved and suctioned through the cutting window of the disposable blade.

F. Indications for Use

The TRUCLEAR™ Incisor® Plus Blade 2.9 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. The TRUCLEAR™ Incisor® Plus Blade 2.9 is used specifically with the TRUCLEAR Hysteroscopic Morcellator.

The TRUCLEAR Hysteroscopic Morcellator includes:

- TRUCLEAR Control Unit
- TRUCLEAR Footswitch
- TRUCLEAR Handpiece

G. Comparison of Technological Characteristics

The TRUCLEAR™ Incisor® Plus Blade 2.9 has the same fundamental technological characteristics as the unmodified predicate device and is substantially equivalent in design, materials and intended use as the unmodified predicate device. The proposed TRUCLEAR™ Incisor® Plus Blade 2.9 has the following similarities as the predicate device cleared in K031787:

- The same indications for use
- Utilizes the same operating principle
- Incorporates the same basic mechanical design
- Manufactured under the same Quality System

The modifications to the proposed device as compared to the predicate device include:

1. Reducing the overall diameters of the inner and outer blade shafts.
2. Increasing the working length of the blade.
3. Addition of a metal sleeve covering the proximal portion of the outer tube.

The reduction in overall diameters of the blade shafts allows the blade to be used with an appropriate sized hysteroscope in office settings. The increase in the blade working length was necessary in order to be compatible with the TRUCLEAR Operative Hysteroscope.

The addition of the metal sleeve on the proximal end of the outer tube replicates the same diameter as the predicate 4.0 Rotary blade device.

There are no significant differences between the proposed and predicate devices that raise new questions of safety or efficacy.

H. Summary Performance Data

The TRUCLEAR™ Incisor® Plus Blade 2.9 performance testing has demonstrated that the proposed device is substantially equivalent to the predicate device and the proposed modifications to the size and length of the blade does not raise new questions of safety and efficacy. Performance testing consisted of a material shed test and a cutting performance test. The Shed Test demonstrated that after 6 minutes of continuous use in water the TRUCLEAR™ Incisor® Plus Blade 2.9 met the established criteria of the visual aid ranking scheme. The Cut Performance Test demonstrated that after running the blade for 15 minutes under simulated use conditions there was no seizing or mechanical failure of the blade.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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

MAR 25 2011

Re: K103389
Trade Name: TRUCLEAR™ Incisor® Plus Blade 2.9
Regulation Number: 21 CFR §884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: March 1, 2011
Received: March 2, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103389

Device Name: TRUCLEAR™ Incisor® Plus Blade 2.9

Indications For Use:

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- TRUCLEAR Control Unit
- TRUCLEAR Footswitch
- TRUCLEAR Handpiece

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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103389