K112134

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NOV 2 2 2011

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 TRUCLEAR Operative Hysteroscope
Date Prepared: July 15, 2011

A. Submitter's Name:
Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road,
Andover MA. 01810

B. Company Contact
Janice Haselton
Sr. Regulatory Affairs Specialist
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C. Device Name

Trade Name:	Smith & Nephew TRUCLEAR Operative Hysteroscope
Common Name:	Hysteroscope
Classification Name:	Hysteroscope and Accessories per CFR §884.1690

D. Predicate Device

The predicate device is the Smith & Nephew Operative Hysteroscope cleared in K013870.

E. Description of Device
Smith & Nephew's TRUCLEAR Operative Hyteroscope is a rigid hysteroscope that is intended for use in office based, hospital and ambulatory surgical centers. The operative hysteroscope incorporates an optical fiber bundle design in order to reduce the overall diameter of the needle portion of the hysteroscope and still provide adequate space in the working channel for instrumentation. The Smith & Nephew TRUCLEAR Operative Hysteroscope internal design consists of a "D" shaped working channel into the needle portion of the hysteroscope. The working channel also acts as an inflow-channel.

F. Intended Use
The Smith & Nephew TRUCLEAR Operative Hysteroscope is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.

G. Comparison of Technological Characteristics

The Smith & Nephew TRUCLEAR Operative Hysteroscope 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 Smith & Nephew TRUCLEAR Operative Hysteroscope has the following similarities as the predicate device cleared in K013870:

- the same indications for use
- utilizes the same operating principle
- incorporates the same basic mechanical design.
- manufactured under the same Quality System.

The Smith & Nephew TRUCLEAR Operative Hysteroscope differs from the predicate Smith & Nephew Operative Hysteroscope cleared in K013870 in that:

- The overall diameter of the operative hysteroscope with sheath has been reduced from 9 mm to a minimum of 5.5 mm.
- The rod/lens design has been replaced by an imaging bundle. The imaging bundle transmit the image similar to the rod/lens design as both designs relay an image through a fiber bundle or rod/lenses from the objective lens to the eyepiece.
- The working length of the operative hysteroscope and sheath has been increased.

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

H. Summary Performance Data

The Smith & Nephew TRUCLEAR Operative Hysteroscope optical performance testing has demonstrated that the operative hysteroscope is substantially equivalent to the predicate Smith & Nephew Operative Hysteroscope (K013870). Optical performance tests included brightness, vignetting, resolution, near and far focus, image run out, depth of field and image distortion testing.

Performance tests included sheath force testing and working channel instrument compatibility testing.

Optical and performance testing demonstrated that the Smith & Nephew TRUCLEAR Operative performed comparably under similar conditions.

Additionally, the Smith & Nephew TRUCLEAR Operative Hysteroscope complies with applicable portions of IEC 60601-2-18 and IEC 60601 electrical standards and has successfully passed cleaning and sterilization validations per AAMI TIR 30 and AAMI TIR 12.

All materials have been demonstrated to meet biocompatibility requirements according to *FDA General Program Memorandum #G95-1, Use of International Standards ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing".*

In conclusion, the optical and performance testing demonstrates that the proposed device is as safe, effective and performs as well as or better than the predicate.

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
Sr. Regulatory Affairs Specialist
Smith & Nephew, Inc.
150 Minuteman Road
ANDOVER MA 01810

NOV 2 2 2011

Re: K112134
Trade/Device Name: Smith & Nephew TRUCLEAR Operative Hysteroscope
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: October 25, 2011
Received: October 26, 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): K112134

Device Name: Smith & Nephew TRUCLEAR Operative Hysteroscope

Indications For Use:

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

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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 K112134