DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 2, 2015

Smith & Nephew, Inc.
Bradley Heil
Regulatory Affairs Manager
150 Minuteman Road
Andover, MA 01810

Re: K152143
Trade/Device Name: TRUCLEAR Operative Hysteroscope 5C and Sheath 5C.
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: July 31, 2015
Received: August 3, 2015

Dear Bradley Heil,

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152143

Device Name
TRUCLEAR Operative Hysteroscope 5C and Sheath 5C

Indications for Use *(Describe)*
The Smith & Nephew TRUCLEAR Operative Hysteroscope 5C and Sheath 5C are used to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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We are smith&nephew

Submitted by:	Smith & Nephew, Inc. 150 Minuteman Rd Andover, MA 01810
Date of Summary:	September 1, 2015
Contact Person and Address:	Bradley Heil Regulatory Affairs Manager T 901-399-6339 F 901-566-7831
Name of Device:	TRUCLEAR Operative Hysteroscope 5C and Sheath 5C
Common Name:	Hysteroscope and Accessories
Device Classification Name and Reference:	Class II 21 CFR 884.1690 Hysteroscope and Accessories
Panel Code:	Obstetrics and Gynecological
Product Code:	HIH

Table 1: Substantially Equivalent Predicates to the TRUCLEAR Operative Hysteroscope 5C & Sheath 5C

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	TRUCLEAR Operative Hysteroscope 5.0 and Sheath 5.6	K112134	11-22-2011

Device Description

The subject TRUCLEAR Operative Hysteroscope 5C and TRUCLEAR Sheath 5C are modifications to the TRUCLEAR Operative Hysteroscope 5.0 and TRUCLEAR Sheath 5.6 previously cleared in K112134. The TRUCLEAR Operative Hysteroscope 5C is a rigid hysteroscope with a slanted distal tip 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.

Intended Use

The Smith & Nephew TRUCLEAR Operative Hysteroscope 5C and Sheath 5C are used to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

Technological Characteristics

Device comparisons described in this premarket notification, including the proposed changes of a slanted distal tip, a change in outer diameter, and the movement of the outflow holes, demonstrate that the proposed hysteroscope and sheath are substantially equivalent to the legally marketed predicate devices (listed above in *Table 1*) with regard to intended use, indications for use, and performance characteristics.

Summary of Pre-Clinical Testing

To further support a determination of substantial equivalence, non-clinical bench testing was conducted to support the proposed hysteroscope and sheath. Test results demonstrated that the proposed devices are substantially equivalent to the previously cleared predicate devices listed above. The specific types of non-clinical testing conducted are listed below.

- *Dimensional Inspection testing* was conducted to show that all devices met drawing dimensions and that all scopes could be assembled with all sheaths.
- *Flow and Visualization testing* was also performed on the proposed devices. All devices showed an average time to attain clear vision was 14.2 seconds.
- *Insertion Force testing* of the proposed devices showed an average 29% reduction in insertion force compared to the predicate devices.
- *Packaging/Ship Testing with visual inspection and functional testing* showed that product will not be damaged during shipping and will function properly post-shipping

Conclusion

As previously noted, this Special 510(k) Premarket Notification is being submitted to request clearance for TRUCLEAR Operative Hysteroscope 5C and Sheath 5C. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to the predicate operative hysteroscope/sheath listed above in *Table 1*.