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

November 22, 2016

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

Re: K161763
Trade/Device Name: Truclear Ultra Mini Tissue Removal Device
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: Class II
Product Code: HIH
Dated: November 11, 2016
Received: November 17, 2016

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,

Benjamin R. Fisher -S

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)* K161763

Device Name
TRUCLEAR ULTRA Mini Tissue Removal Device

Indications for Use *(Describe)*
The TRUCLEAR Tissue Removal Devices are intended for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as:
Submucous myomas
Endometrial polyps
Retained products of conception

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.

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510(k) Summary

K161763

Submitted by:	Smith & Nephew, Inc. 150 Minuteman Road Andover, MA 01810
Date of Summary:	November 18, 2016
Contact Person and Address:	Bradley Heil Regulatory Affairs Manager T 901-216-6884 F 901-566-7831 Bradley.heil@smith-nephew.com
Name of Device:	TRUCLEAR ULTRA MINI Tissue Removal Device
Common Name:	Hysteroscopic Tissue Removal Device
Device Classification Name and Reference:	21 CFR 884.1690 Hysteroscope and Accessories
Device Class:	Class II
Panel Code:	Obstetrics and Gynecology
Product Code:	HIH (Hysteroscope and accessories)
Predicate Device	TRUCLEAR ULTRA PLUS Tissue Removal Device (K132015) The predicate device has not been subject to a design related recall.
Reference Device	TRUCLEAR INCISOR Tissue Removal Device (K132015)

Device Description

Smith & Nephew's TRUCLEAR ULTRA Mini Tissue Removal Device is a single use device that hysteroscopically removes intra-uterine tissue. The device consists of a stainless steel inner tube that rotates and reciprocates inside a stainless steel outer tube. The proximal ends of the tubes are enclosed within a plastic housing. The housing is engaged with the TRUCLEAR Handpiece which drives the inner tube of the device. The inner tube has a sharp cutting edge that resects tissue in the cutting window at the distal end of the outer tube. The resected tissue is simultaneously aspirated out of the uterine cavity using suction.

Indications for Use
The TRUCLEAR Tissue Removal Devices are intended for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as:
Submucous myomas
Endometrial polyps
Retained products of conception

The indication for use statement for the subject device is identical to the predicate device.

Comparison of Technological Characteristics

	TRUCLEAR ULTRA Mini (Subject Device)	TRUCLEAR ULTRA PLUS Device (Predicate Device)
Principle of Operation	Mechanical Resection	Mechanical Resection
Style of Device	Reciprocating	Reciprocating
Scope used	TRUCLEAR 5.0 or 5C Hysteroscope	TRUCLEAR 8.0 Hysteroscope
Outer and inner shaft	304 Stainless Steel 440 Stainless steel	304 Stainless Steel 465 Stainless Steel
Coating	Chromium coating	none
Inner shaft Lubricant	Silicone	Silicone
Sterility	EtO	EtO
Single Use	Yes	Yes

Substantial Equivalence Information
The subject device has different technological characteristics compared to the predicate device.

The differences between the subject device and the predicate do not raise different types of safety and effectiveness questions, as these differences have been evaluated in previous 510(k) submissions for hysteroscopic tissue removal devices. The differences in technological characteristics can be evaluated through bench testing. The differences in material can be evaluated through biocompatibility assessment.

Summary of Pre-clinical Testing
To further support a determination of substantial equivalence, non-clinical bench testing was conducted to support the subject device. The specific types of non-clinical testing conducted are listed below.

- Shed Test- A shed test was conducted to determine the relative wear of the blade during use. Results from the testing showed an acceptable level of shedding.
- Cutting Performance Test- A cutting performance test was conducted to demonstrate the durability and robustness of the device to show the ability to function for 20 minutes of activation. Results from the testing demonstrated that the subject devices met the acceptance criteria.
- Resection Rate Test- A resection rate test was conducted to evaluate the performance of the device in terms of an acceptable resection rate. Results from the testing verified that the subject device met the acceptance criteria showing an acceptable resection rate.
- Biocompatibility Testing- Cytotoxicity, sensitization, and irritation testing were conducted along with a chemical analysis of the extract. Results from the testing show the device to be acceptable for biological use.
- Shelf Life Testing- Accelerated age testing along with post-aging performance testing was conducted and justifies the shelf life of the device.

The reference predicate, TRUCLEAR INCISOR, addresses any differences in materials and performance testing between the subject and primary predicate devices. In addition, a risk analysis was conducted to show that any residual risks are outweighed by the medical benefit.

Conclusion

Based on the performance data provided, the subject device is substantially equivalent to the proposed predicate device.