August 29, 2018

Covidien
Heather L. Harvey, MS, RAC
Regulatory Affairs Specialist
60 Middletown Ave.
North Haven, CT 06473

Re: K180496
Trade/Device Name: TruClear™ Elite Hysteroscopes
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: II
Product Code: HIH
Dated: July 27, 2018
Received: July 30, 2018

Dear Heather L. Harvey:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sharon M. Andrews -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180496

Device Name
TruClear™ Elite Hysteroscopes

Indications for Use *(Describe)*
The TruClear Elite Hysteroscope is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and operative 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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510(k) Summary
K180496

Date Prepared:
February 23, 2018

Submitter:
Covidien
60 Middletown Avenue
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Contact:
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Regulatory Affairs Specialist
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Name of Device:

Trade/Proprietary Name:	TruClear™ Elite Hysteroscopes
Common Name:	Hysteroscope
Class:	Class II
Regulation:	21 CFR 884.1690, Hysteroscope and Accessories
Panel Code	Obstetrics and Gynecology
Product Code:	HIH (Hysteroscope and accessories)

Predicate Device:

Trade/Proprietary Name:	Smith & Nephew TRUCLEAR Operative Hysteroscope 8.0 & Smith & Nephew TRUCLEAR Operative Hysteroscope 5C
Common Name:	Hysteroscope
Classification Name:	Hysteroscope & Accessories, HIH, 21 CFR 884.1690
510(k) Number:	K013870, K152143
Manufacturer:	Smith & Nephew, 150 Minuteman Drive, Andover, MA

The predicate devices have not been subject to a design related recall.

Device Description:
TruClear™ Elite Hysteroscopes are reusable instruments for use in visualizing the uterine cavity and performing diagnostic and operative procedures. The TruClear™ Elite Hysteroscopes are stainless steel instruments designed with a rod-lens optical channel for visualization, optical fibers for illumination, and a working channel to permit introduction of instrumentation.

The subject Truclear™ Elite Hysteroscopes Plus (7.25mm) and Mini (6mm) are modifications to the previously cleared Smith & Nephew Operative Hysteroscopes 8.0 (K013870) and 5C (K152143). Both the Truclear™ Elite Plus and Mini Hysteroscopes are rigid hysteroscopes with a slanted distal tip, rod lens optics and disposable proximal fluid seal.

The TruClear™ Elite Hysteroscopes are composed of the working channel insert and the hysteroscope body. The device is designed to be disassembled for access to interior lumens during cleaning and sterilization. Like the predicate devices, the subject devices have an inflow and outflow channel to provide continuous flow during the clinical procedure. The inflow channel passes through the hysteroscope body and provides operative fluid from a fluid management system or pressurized saline bag to distend the uterine cavity. The outflow channel which is contained within the working channel insert, clears the uterine cavity to maintain visualization. The outflow channel also acts as the instrument channel through which the tissue removal device is inserted.

Indications for Use:
The TruClear Elite Hysteroscope is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedures.

Predicate Device Comparison:

Device & Predicate Device(s):	K013870	K152143	K180496 Truclear Elite Hysteroscope Plus	K180496 Truclear Elite Hysteroscope Mini
Indication for Use Statement	The Smith & Nephew Operative Hysteroscope and Accessories are used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures	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.	The TruClear™ Elite Hysteroscope is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedures	The TruClear™ Elite Hysteroscope is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedures
Materials of Construction	Stainless Steel, PEEK, Sapphire, Optical Glass	Stainless Steel, PEEK, Sapphire, Optical Glass	Stainless Steel, PEEK, Sapphire, Optical Glass	Stainless Steel, PEEK, Sapphire, Optical Glass
Device Components				
Dimensions				
Working Length (mm)	191.5 (scope) 168 (sheath)	219 (scope) 205 (sheath)	201.1	201.1
Overall Channel Length (mm)	280	334	Not provided	Not provided
Outer Diameter (mm)	8.5	5.25	7.25	6
Working Channel Diameter (mm)	[D shaped 5.5 by 5.4]	[D shaped 5.5 by 5.4]	4.2	3.1
Device Design				
Distal Tip Shape	Flat	Slanted	Slanted	Slanted
Working Channel Closure	Stopcock	Stopcock	Seal	Seal
Compatible Light Source				
Recommended Light source	Metal Halide and Xenon	Metal Halide and Xenon	Metal Halide and Xenon	Metal Halide and Xenon
Power Rating of Light source (watts)	≤ 300 W	≤ 300 W	≤ 300 W	≤ 300 W
Optics				
Objective lens				
Focal Length (mm)	1.3	0.6	1.02	1.02
Working Distance (mm)	30	10	30	30
Field of View (Degrees)	80	85	80	80
Direction of view (Degrees)	0	0	0	0

Optics	Rod lens	Fiber optic (Image bundle)	Rod lens	Rod lens
Illumination fibers				
Ratio of Luminous Energy Transmitted to Energy Delivered	23.5% (12%)	15.6% (12.8%)	23.5%	23.5%
Image Transmission System	Not provided	Not provided	Rod lens	Rod lens
Eyepiece				
Eyepiece Magnification	21x	37x	19.4x	19.4x
Image Quality				
Resolution @ 30 mm Working Distance (lp/mm)	8.5	3	8	8
Distortion	-26% barrel	-23% barrel	-22% barrel	-22% barrel

The subject and predicate device have the same intended use.

The subject and predicate devices have different technological characteristics, including dimensions, device design, and optical characteristics. These differences do not raise different questions of safety and effectiveness.

Summary of Performance 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.

1. Insertion Force Test
2. Flow Performance Test
3. Seal Performance Leak Test
4. Image Quality Testing
5. Use Life Testing of Hysteroscopes
6. Shelf Life of Hysteroscope Seal (Functional Performance and Package Integrity)
7. Biocompatibility
8. Reprocessing Validation of Hysteroscope
9. Sterilization Validation of Hysteroscope Seal
10. Seal Integrity Testing
11. Distribution Testing
12. Electrical Safety Testing per IEC 60601-1:2005
13. EMC Testing per IEC 60601-2-18:2009
14. Usability Testing per IEC 62366-1:2015

Conclusion:
The TruClear™ Elite Hysteroscopes were found to be substantially equivalent to the predicate device.