May 16, 2019

Meditrina, Inc.
Csaba Truckai
President & CEO
1601 S. De Anza Blvd, Suite 165
Cupertino, CA 95014

Re: K190372
Trade/Device Name: Aveta System
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: Class II
Product Code: HIH, HIG
Dated: February 14, 2019
Received: February 15, 2019

Dear Csaba Truckai:

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
Assistant Division Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K190372

Device Name
Aveta System

Indications for Use *(Describe)*
The Aveta System is intended for intrauterine use by trained gynecologists to permit viewing of the cervical canal and the uterine cavity, provide liquid distension of the uterus and monitor the volume differential between the irrigation fluid flowing into and out of the uterus during diagnostic and surgical procedures to resect and remove tissue such as submucous myomas, endometrial polyps and 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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K190372: 510(k) Summary

I. Submitter Information

Submitter name:	Meditrina, Inc. 1601 S. De Anza Blvd, Suite 165 Cupertino, CA 95014
Contact person:	Csaba Truckai President & CEO Mobile: (415) 215-7233 Fax: (408) 609-3342 Office: (408) 471-4877 csabat@hermesinnovations.com
Date Prepared:	14 February 2019

II. Product Classification

Device Name:	Aveta System

Common Name:	Hysteroscope	Subject Device
Regulation:	21 CFR 884.1690	
Regulation Name:	Hysteroscope and accessories	
Class:	II	
Product Code:	HIH	
Additional Product Codes:	HIG	

III. Predicate Device Information

Predicate Devices	Manufacturer	Predicate Device Names	510(k)#	Clearance Date
PREDICATE DEVICE (System) ***(see NOTE 1)***	Smith & Nephew (Truclear Morcellation System)	Truclear Operative Hysteroscope 5C and Sheath 5C	K152143	September 2, 2015
		Hysteroscopic Fluid Management System ***(see NOTE 2)***	K123732	April 4, 2013
		Truclear Morcellator System and Truclear Morcellators	K132015	March 18, 2005

NOTE 1: The Smith & Nephew Truclear Morcellation System (Controller, Hysteroscope and Fluid Management System) was originally cleared under K031787 as a system. Since the original clearance each system component has been modified per the 510(k) clearances noted above.

NOTE 2: Originally cleared as IUR Fluid Management System / Hysteroscopy Pump HM6 by W.O.M. World of Medicine AG under K123732.

Predicate has not been a subject of a design related recall.

IV. Device Description

The Aveta System is an integrated system which allows for visualization of the cervical canal and the uterine cavity for the purpose of performing diagnostic and operative hysteroscopic procedures.

The Aveta System consists of the components listed in Table 1. The system includes a Controller with integrated fluid management which incorporates a dual peristaltic pump design to control the continuous inflow and outflow of saline to provide fluid distention of the uterine cavity. The Controller provides continuous monitoring of the intrauterine pressure to the set pressure, as well as monitoring of the volume differential between saline inflow and outflow from the uterus. The Controller connects to a sterile, single use Disposable Hysteroscope via a Reusable Hysteroscope Handset that allows visualization of the cervical canal and the uterine cavity and displays the images obtained from the hysteroscope on a standard monitor. For operative procedures, the Aveta System includes a sterile, mechanical Disposable Resecting Device powered by a motorized, Reusable Resecting Handset which is inserted through the sterile hysteroscope working channel to resect and remove endometrial polyps, submucous myomas and retained products of conception under suction.

Table 1. Aveta System Components

Aveta System Component	Functions Performed
Aveta Controller with Integrated Fluid Management	• Hysteroscopic image / video processing / storing recorded images • Fluid Management with irrigation and aspiration functions • Controls saline inflow and outflow for insufflation of the uterine cavity for visualization • Monitors and maintains intrauterine pressure to set pressure • Monitors volume differential (fluid deficit) • Controls Mechanical Resecting Device oscillation (Preset speed) • Displays image/video and procedural information on external monitor
Aveta Disposable Hysteroscope (with tubing and fluid management cassette) Aveta Reusable Hysteroscope Handset	• Visualization of uterine cavity • Provides conduits/lumens for fluid inflow and outflow • Provides membrane in fluid inflow line to enable intrauterine pressure monitoring/control using pressure transducer in Controller • Includes cassette for proper connection with Controller pumps • Provides conduit for Disposable Resecting Device for operative hysteroscopy • Provides user interface for intrauterine set pressure and fluid deficit limit adjustments, and recording of images
Aveta Disposable Resecting Device Aveta Reusable Resecting Handset	• Mechanically resects and removes tissue under suction • Includes motor to provide oscillation of resection tip
Additional Aveta System Components / Accessories • Monitor • Waste Management Kit • Scale • Roll Stand	 • Displays image, procedural parameters and notifications • Collects tissue for pathology and stores the outflow fluid waste • Measures waste fluid / leaked fluid lost from cervix / hysteroscope • Mounts Controller and Monitor

V. Indications for Use

Comparison of Indications for Use

Device	Indications For Use
Aveta System (Subject Device)	The Aveta Diagnostic and Therapeutic Hysteroscopy System is intended for intrauterine use by trained gynecologists to permit viewing of the cervical canal and the uterine cavity, provide liquid distension of the uterus and monitor the volume differential between the irrigation fluid flowing into and out of the uterus during diagnostic and surgical procedures to resect and remove tissue such as submucous myomas, endometrial polyps and retained products of conception.
Predicate System Component: **Truclear™ Morcellator System and Truclear™ Morcellators** **(K152143)**	For intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as submucous myomas, endometrial polyps and retained products of conception.
Predicate System Component: **Hysteroscopic Fluid Management System (K123732)**	To provide liquid distension of the uterus for diagnostic and operative hysteroscopy, and to monitor the volume differential between the irrigation fluid flowing into and out of the uterus.
Predicate System Component: **Truclear™ Operative Hysteroscope 5C and Sheath 5C (K132015)**	To permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.

Although the subject device does not have identical indications compared to the individual predicate devices, the subject device has the same general intended use as each of the respective predicate components: 1) to permit viewing of the cervical canal and the uterine cavity during diagnostic and operative procedures, 2) to provide liquid distension of the uterus and monitor fluid volume differential, and 3) to resect and remove tissue such as submucous myomas, endometrial polyps, and retained products of conception. When comparing each component function of the subject device to the indications of the respective predicate components, the subject and predicate devices have the same intended use.

VI. Comparison of Technological Characteristics with the Predicate Device

Aveta System and the predicate system have similar technological characteristics in terms of basic operating principle and basic design features with minor differences.

Technological Comparison of Aveta System with Predicate System

	Subject Device	Predicate Devices (System) [Original K031787]			Reference Device
510k#	**TBD**	**K132015**	**K123732**	**K152143**	**K123151**
Manufacturer:	**Meditrina Inc.**	**Smith and Nephew, Inc.**			**Endosee Corporation (Cooper Surgical)**
Device Names	**Aveta System**	**Truclear™ Morcellator System and Truclear™ Morcellators**	**Hysteroscopic Fluid Management System**	**Truclear™ Operative Hysteroscope 5C and Sheath 5C**	**Endosee® U-Scope Model 8000**
CONTROLLER FUNCTIONS					
Hysteroscope Functions					
Visualization and Image Processing	CMOS sensor and light source in Hysteroscope and image processed by the Controller microprocessor	N/A	N/A	Regular Optics with CCD sensor and light source and camera; images process by Controller	CMOS sensor, and light source in Hysteroscope and image processed by internal microprocessor in reusable handset
Viewing Functions	Controller connects to a separate Monitor for diagnostic and operative information; Screen displays IU pressure, fluid deficit with graphical user interface.	N/A	Pressure and Fluid Deficit data is displayed on the unit. Image is displayed on the Monitor.	N/A	Monitor integrated in the Reusable Handset Camera
Fluid Management Functions					
Fluid Distention	Continuous flow of saline/fluid	N/A	Same	N/A	Saline inflow
Irrigation for Distention	Peristaltic pump with dual pressure sensors for irrigation of fluids	N/A	Same	N/A	N/A
Aspiration	Peristaltic pump for aspiration of fluids and for resected tissue and fluids	N/A	Facility vacuum pump provides suction for aspiration of resected tissue and fluids	N/A	N/A
Intrauterine Pressure Measurements	Obtains two independent intrauterine pressure measurements by sensing pressure of the irrigation tube	N/A	Same	N/A	N/A
Set Pressure Range	30-120 mmHg	N/A	15-120 mmHg	N/A	N/A
Set Pressure User Adjustments	Allows user to increase/decrease the set pressure	N/A	Same	N/A	N/A

	Subject Device	Predicate Devices (System) [Original K031787]			Reference Device
510k#	**TBD**	**K132015**	**K123732**	**K152143**	**K123151**
Manufacturer:	**Meditrina Inc.**	**Smith and Nephew, Inc.**			**Endosee Corporation (Cooper Surgical)**
Device Names	**Aveta System**	**Truclear™ Morcellator System and Truclear™ Morcellators**	**Hysteroscopic Fluid Management System**	**Truclear™ Operative Hysteroscope 5C and Sheath 5C**	**Endosee® U-Scope Model 8000**
Pressure Relief for overpressure risk mitigation	Reverse rotation of irrigation peristaltic pump at 150 mmHg	N/A	Same	N/A	N/A
Over Pressure Controls	Above 100 mmHg requires positive action by the user with two presses to confirm setting is intentional up to 120 mmHg max. Display Notification appears.	N/A	Same	N/A	N/A
User Pressure Adjustments to Set Pressure	5 mmHg at a time up to 120 mmHg max.	N/A	Same	N/A	N/A
Fluid Deficit Measurement (Weight based measurement which includes aspirated fluid and fluid leaking from cervix)	Obtains difference between three independent weight measurement sensors to determine the Fluid Deficit: 1) Irrigation minus 2) Aspiration and 3) fluid lost from cervix as measured by scale	N/A	Obtains difference between two independent weight measuring sensors to determine Fluid Deficit	N/A	N/A
Flow Rate	180-500 mL/min preset fixed flow rates	N/A	30-700mL/min user adjustable	N/A	N/A
Mechanical Resection Functions					
Mechanical Resecting Device	Connects to the Disposable or Reusable Resecting Handset by an electrical connection to provide a dc motor control with a preset programmed motor oscillation speed.	Same	N/A	N/A	N/A
HYSTEROSCOPE SYSTEM					
Disposable Hysteroscope					
Irrigation and Aspiration Lumens	Independent sterile saline irrigation and aspiration lumens	N/A	N/A	Same	Independent sterile irrigation lumen. No aspiration lumen
Insertion OD	5.5 mm	N/A	N/A	5.7 mm	Oval - 3.8mm x 4.6 mm
Working Length	224 mm	N/A	N/A	205 mm	287 mm

	Subject Device	Predicate Devices (System) [Original K031787]			Reference Device
510k#	**TBD**	**K132015**	**K123732**	**K152143**	**K123151**
Manufacturer:	**Meditrina Inc.**	**Smith and Nephew, Inc.**			**Endosee Corporation (Cooper Surgical)**
Device Names	**Aveta System**	**Truclear™ Morcellator System and Truclear™ Morcellators**	**Hysteroscopic Fluid Management System**	**Truclear™ Operative Hysteroscope 5C and Sheath 5C**	**Endosee® U-Scope Model 8000**
Illumination	LEDs (Light Emitting Diode)	N/A	N/A	Fiber optic	LED (Light Emitting Diode)
Working Channel	3.5 mm working channel	N/A	N/A	3 mm working channel	No working channel
Camera	Digital CMOS Camera	N/A	N/A	Fiberoptic image guide coupled to External CCD (not part of the system)	Same
Proximal Connection (to Camera and Light Controls)	Entire device including the cable and handset is sterile in one package	N/A	N/A	Mechanical connection to the reusable remote camera head and light cable	Electromechanical connection at the proximal end to Reusable Handle
Reusable Hysteroscope Handset					
Image Processing	Processes images generated by the Disposable Hysteroscope CMOS sensor	N/A	N/A	No images processing capabilities. Images are processed by the external CCD video camera attached to Endoscope eye piece (not part of the system)	Same
User Controls	• Set Pressure Controls • Fluid Deficit Limit Controls • Image capture capability • Mode Selection with preprogrammed flowrates for each Mode	N/A	• Set Pressure Controls • Fluid Deficit Limit Controls • Flow Rate Adjustment	• Light, Image adjustments and Image Capture using compatible device	• Image capture button. • Increase illumination power button. • ON/OFF button. • Touch screen for patient ID, time set entry
RESECTING SYSTEM					
Disposable Resecting Device					
Cutting Window	8 mm	7 mm	N/A	N/A	N/A
Blade Material	Stainless steel	Same	N/A	N/A	N/A
Working Length	328 mm	357 mm	N/A	N/A	N/A
Insertion OD	3.4 mm	2.9 mm	N/A	N/A	N/A

	Subject Device	Predicate Devices (System) [Original K031787]			Reference Device
510k#	**TBD**	**K132015**	**K123732**	**K152143**	**K123151**
Manufacturer:	**Meditrina Inc.**	**Smith and Nephew, Inc.**			**Endosee Corporation (Cooper Surgical)**
Device Names	**Aveta System**	**Truclear™ Morcellator System and Truclear™ Morcellators**	**Hysteroscopic Fluid Management System**	**Truclear™ Operative Hysteroscope 5C and Sheath 5C**	**Endosee® U-Scope Model 8000**
Device Rotation for Resection	Rotatable distal portion of the hub allows the user to orient the resection window towards the target tissue	Not rotatable. User must turn Resecting Handset to orient window direction for resection	N/A	N/A	N/A
Aspiration During Resection	Aspiration is provided via peristaltic suction pump	Aspiration provided by facility vacuum pump	N/A	N/A	N/A
Tissue Collection	Tissue catch provided for resected tissue chips	Same	N/A	N/A	N/A
Disposable (Sterile) and Reusable (Steam Sterilizable) Resecting Handset					
Resection Mechanism	Mechanical	Mechanical	N/A	N/A	N/A
User Controls	Handset Controls	Foot Switch Controls	N/A	N/A	N/A
Mechanical Connection	Locks Disposable Resecting Device	Locks Disposable Resecting Device	N/A	N/A	N/A
Rotational Speed	1500 RPM (pre-set – not user adjustable)	100 – 2500 RPM (user adjustable)	N/A	N/A	N/A
WASTE MANAGEMENT KIT					
How Provided	Non-sterile, Single-Use	N/A	Facility provided (Not part of the system). Non-sterile, Single-Use	N/A	N/A

The differences outlined were evaluated through performance testing to demonstrate safety and effectiveness of the Aveta System. The differences in technological characteristics do not raise different questions of safety and effectiveness

VII. Performance Data

The following performance data have been provided in support of the substantial equivalence determination.

- **Software Verification and Validation Testing** performed per IEC 62304:2006 and documentation provided per FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."
- **Other Tests** were performed pre pre-specified test protocols which included:
  - Integrity: System withstands operating pressures
  - Functional Testing: Cut and coagulation, aspiration, irrigation, pressure control
  - Dimensional Inspection and Testing
  - Functional Testing for all components of the system
  - Maximum LED Tip Temperature
  - Fluid Deficit Limit Verification testing
  - Simulated Use: Tissue resection, regulation of cavity pressure, imaging
  - Comparative testing to predicate for pressure control, fluid deficit, fluid control and durability.
  - Biocompatibility Testing per ISO 10993-1:2009/(R)2013.
  - Sterilization Validation per ISO 11135:2014 and ISO 11137-1/-2/-3:2013.
  - Packaging Validation per ASTM D4169:2016.
  - Accelerated Aging per ASTM F1980:2016.
  - Electrical Safety & EMC: In accordance with IEC 60601-1:2005, IEC 60601-1-2:2014 and IEC 60601-2-18:2009.
  - Usability Testing per FDA guidance and IEC 62366:2015

VIII. Conclusions

The Aveta System is substantially equivalent to the Smith and Nephew Truclear System based on the similarities in intended use / indications for use, as well as technological characteristics and principles of operation.

The performance testing provided in the subject premarket notification demonstrate that the Aveta System is as safe and effective as the predicate device for its proposed indications for use.