October 1, 2019

Meditrina, Inc.
Csaba Truckai
President & CEO
1190 Saratoga Avenue, Suite 180
San Jose, CA 95129

Re: K191958
Trade/Device Name: Aveta System
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH, HIG
Dated: August 30, 2019
Received: September 3, 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Sharon Andrews
Assistant 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)*
K191958

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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K191958: 510(k) Summary

I. Submitter Information

Submitter name:	Meditrina, Inc. 1190 Saratoga Avenue, Suite 180 San Jose, CA 95129
Contact person:	Csaba Truckai President & CEO Mobile: (415) 215-7233 Fax: (408) 418-4815 Office: (408) 471-4877 csabat@hermesinnovations.com
Date Prepared:	30 September 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 (21 CFR 884.1700)	

III. Predicate Device Information

Predicate Devices	Manufacturer	Predicate Device Names	510(k)#	Clearance Date
Predicate Device	Meditrina, Inc.	Aveta System	K190372	May 16, 2019

The predicate has not been a subject of a design related recall.

IV. Device Description

The modified Aveta System is used by physicians in an office or operating room setting. The Aveta Controller acts as the hub of the system. For diagnostic procedures, the Aveta Fluid Management Accessory, the Aveta Handswitch, the Aveta Scale, the Waste Management Bags, saline bags and an external monitor are all connected to the Aveta Controller. The inflow and outflow of the fluid management accessory are connected to the corresponding ports of a compatible hysteroscope. For therapeutic procedures, the Aveta Reusable Resecting Handset or the Aveta Disposable Resecting Handset are connected to the Aveta Controller for powering the Aveta Disposable Resecting Device. Provided in Table 1 are additional details on the components of the modified Aveta System.

Table 1. Modified Aveta System Components

Aveta System Component	Device Characteristics	Materials; Patient Contact and Contact Duration*	Functions Performed
Aveta Controller with Integrated Fluid Management (P/N 212-002)	Non-sterile, reusable, used outside the sterile field	No patient contact	• Hysteroscopic image / video processing / storing recorded images • Fluid Management with irrigation and aspiration functions

Aveta System Component	Device Characteristics	Materials; Patient Contact and Contact Duration*	Functions Performed
			• 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 Fluid Management Accessory (P/N 205-023)	Sterile (EO), single use, used in the sterile field	Polymers (PVC, ABS); indirect patient contact for limited duration.	• 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
Aveta Disposable Resecting Device (P/N 204-003)	Sterile (Gamma), single use, used in the sterile field	Stainless steel, polymers (ABS); direct contact with patient for limited duration.	• Mechanically resects and removes tissue under suction
Aveta Disposable Resecting Handset (P/N 211-001)	Sterile (Gamma), single use, used in the sterile field	Stainless steel, ABS; No patient contact	• Includes motor to provide oscillation of resection tip
Aveta Reusable Resecting Handset (P/N 211-001)	Non-sterile, reusable, cleaned and steam sterilized prior to each use	Stainless steel, polymers; No patient contact	• Includes motor to provide oscillation of resection tip
Additional Aveta System Components / Accessories • Monitor • Waste Management Kit (P/N 205-001) • Waste Scale Bag (P/N 205-003) • Aveta Scale (P/N 212-020) • Aveta Roll Stand (P/N 200-020) • Aveta Handswitch (P/N 218-002)	• Non-sterile, reusable • Non-sterile, single use • Non-sterile, single use • Reusable, outside the sterile field • Reusable, outside the sterile field • Reusable, outside the sterile field	(No patient contact with any of the additional accessories) • Non-sterile, reusable • Non-sterile, single use • Polymer • Stainless steel, hardware • Stainless steel, hardware • ABS, hardware	• Displays image, procedural parameters and notifications • Collects tissue for pathology and stores the outflow fluid waste • Collects waste fluid from patient drape • Measures waste fluid / leaked fluid lost from cervix / hysteroscope • Mounts Controller and Monitor • Provides user interface for intrauterine set pressure, fluid deficit limit adjustments and different flow modes.

*: For devices with patient contact, the materials with direct or indirect patient contact were verified for biocompatibility for the contact duration per ISO 10993-1.

V. Indications for Use

The indications for use of the subject device is identical to that of the predicate Aveta System.

Comparison of Indications for Use

Device	Indications For Use
Aveta System (modified) (Subject Device)	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.
Aveta System (Predicate Device)	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.

VI. Comparison of Technological Characteristics with the Predicate Device

The modified Aveta System and the cleared Aveta System have the same technological characteristics in terms of basic operating principles and basic design features with minor differences. The primary difference is the inclusion of a new component, Aveta Handswitch, which allows for the Aveta System to be used with commercially available hysteroscopes.

	Subject Device	**PREDICATE Device**
510k#	**K191958**	**K190372**
Manufacturer:	**Meditrina Inc.**	**Meditrina Inc.**
Device Names	**Aveta System**	**Aveta System**
AVETA CONTROLLER		
	Endoscope Functions (performed by commercially available hysteroscope or the AVETA CONTROLLER)	**Endoscope Functions (performed by AVETA CONTROLLER)**
Visualization and Image Processing	If using commercially available hysteroscope accessories: Regular Optics with CCD sensor, Light Source and Camera Controller from compatible device If using Aveta Disposable Hysteroscope: Identical to predicate (Aveta controller)	CMOS sensor, and light source in Aveta Disposable Hysteroscope with image processing by the Aveta Controller
Image and Procedural Parameter Display	If using commercially available hysteroscope accessories: External Camera Controller connects to an external commercially available Monitor and displays images. If using Aveta Disposable Hysteroscope: Identical to predicate (Aveta Controller)	Aveta Controller connects to a commercially available external Monitor for diagnostic and operative information; Screen displays cavity pressure, fluid deficit with graphical user interface.
Fluid Management Functions (performed by AVETA CONTROLLER)		
Controller:	No change from cleared device	As in K190372
OTHER COMPONENTS (BESIDES CONTROLLER)		
HYSTEROSCOPE		

	Subject Device	PREDICATE Device
510k#	**K191958**	**K190372**
Manufacturer:	**Meditrina Inc.**	**Meditrina Inc.**
Device Names	**Aveta System**	**Aveta System**
Hysteroscope:	• Commercially available hysteroscope and accessories such as: ○ Hologic Myosure XL Hysteroscope (K122563) ○ Covidien (Medtronic) TruClear 8.0 Hysteroscope (K031787) • Aveta Disposable Hysteroscope included in K190372	• Aveta Disposable Hysteroscope ○ 510(k) Cleared per K190372
Fluid Management Control Functions:	• Aveta Handswitch • Aveta Disposable Hysteroscope included in K190372	• Aveta Disposable Hysteroscope ○ 510(k) Cleared per K190372
AVETA FLUID MANAGEMENT ACCESSORY		
Device:	No change from cleared device	As in K190372
AVETA DISPOSABLE RESECTING DEVICE		
Device:	No change from cleared device	As in K190372
AVETA DISPOSABLE RESECTING HANDSET		
Device:	No change from cleared device	As in K190372
SYSTEM ACCESSORIES		
AVETA HANDSWITCH		
How Provided	Non-critical component (Non-sterile, Reusable, used outside the sterile field)	Not included in K190372
Function	Provides user a means to control the fluid management functions	Fluid management functions controlled by cleared Aveta Disposable Hysteroscope.
Cleaning/ Disinfection	Same as that for cleared Aveta System (predicate).	Validated (per AAMI TIR 12 and AAMI TIR 30) instructions in IFU
AVETA WASTE MANAGEMENT KIT		
Device:	No change from cleared device	As in K190372
AVETA WASTE SCALE BAG		
Device:	No change from cleared device	As in K190372
AVETA ROLL STAND		
Device:	No change from cleared device	As in K190372
MONITOR		
Device:	No change from cleared device	As in K190372
AVETA SCALE		

	Subject Device	PREDICATE Device
510k#	**K191958**	**K190372**
Manufacturer:	**Meditrina Inc.**	**Meditrina Inc.**
Device Names	**Aveta System**	**Aveta System**
Device:	No change from cleared device	As in K190372

The modified Aveta System is identical to the cleared Aveta System with the following exceptions:

a) The modified Aveta System allows the cleared Aveta System (per K190372) components to be used in combination with commercially available (non-Meditrina) hysteroscopes instead of the cleared Meditrina Aveta Disposable Hysteroscope. The commercially available (non-Meditrina) hysteroscopes may be:
   - Hologic MyoSure XL Hysteroscope P/N 50-200XL (optional Outflow Channel P/N 50-201XL) (K122563).
   - Covidien (Medtronic) TruClear 8.0 Hysteroscope P/N 7209208 w/ Outer Sheath P/N 7209309 (K031787).

b) When used in combination with commercially available hysteroscopes, the modified Aveta System includes a new accessory called the Aveta Handswitch. The Aveta Handswitch enables a circulating nurse to control fluid management parameters such as flow rate and fluid deficit similar to the controls on the handle of Aveta Disposable Hysteroscope.

Besides the change described above, there is no change to the components of the cleared Aveta System (K190372). The addition of the handswitch and ability for the Aveta System to be utilized with third-party hysteroscopes do not raise different questions of safety and effectiveness.

VII. Non-Clinical Performance Testing

The following summary results of design control activities have been provided in support of the substantial equivalence determination.

- Functional Testing with use of the Aveta Handswitch: Pressure control and flow control verification were performed to ensure the Handswitch controls function as expected.
- Simulated Use with labeled compatible hysteroscopes (TruClear 8.0 and Myosure XL): Regulation of cavity pressure was demonstrated in a model uterine system with the TruClear 8.0 and Myosure XL utilizing the Aveta System in various operational modes (e.g., diagnostic, therapeutic). Results demonstrate the subject device met specifications.

VIII. Conclusions

The subject device has the same intended use as the predicate. Differences in technology, including the ability of the subject device to be utilized with third-party hysteroscopes and the addition of the Aveta Handswitch do not raise different questions of safety and effectiveness. Performance testing evaluating the differences was conducted, and the results of the testing demonstrate that the subject device is as safe and effective as the predicate. Therefore, the subject Aveta System is substantially equivalent to the predicate Aveta System (K190372).