December 19, 2019

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

Re: K192100
Trade/Device Name: Aveta Disposable Hysteroscope
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope And Accessories
Regulatory Class: II
Product Code: HIH
Dated: November 18, 2019
Received: November 21, 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 M. Andrews
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)*
K192100

Device Name
Aveta Disposable Hysteroscope

Indications for Use *(Describe)*
The Aveta Disposable Hysteroscope is 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.

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K192100: 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:	18 December 2019

II. Product Classification

Device Name:	Aveta Disposable Hysteroscope

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

III. Predicate Device Information

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

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

IV. Device Description

The Aveta Disposable Hysteroscope is used by physicians in an office or operating room setting. The subject device includes the Aveta Disposable Hysteroscope and Aveta Controller. Like the Aveta Disposable Hysteroscope cleared under K190372, the modified Aveta Disposable Hysteroscope includes a camera and LED light. The Aveta Disposable Hysteroscope is connected to the Aveta Controller to provide the camera and light functions and to process and store the image obtained from the Aveta Disposable Hysteroscope.

For fluid management, the Aveta Disposable Hysteroscope can be used with gravity fed pressurized saline bag or the fluid management system cleared under K190372. For therapeutic procedures, the Aveta Disposable Hysteroscope is used with the cleared Aveta Disposable Resecting Device (K190372). The only functional buttons on the Aveta Disposable Hysteroscope handle are the image capture and the image transfer buttons. For the modified device, when other buttons on the handle are pressed, the Aveta Controller does not take any action.

Other than minor change to the Aveta Controller software to disable fluid management related buttons on the Aveta Disposable Hysteroscope, there is no change to the components of the cleared Aveta

System (K190372). Provided in Table 1 are additional details on the modified Aveta Disposable Hysteroscope.

Table 1. Modified Aveta Disposable Hysteroscope and accessory

Aveta Disposable Hysteroscope and Accessory	Device Characteristics & Packaging	Materials; Patient Contact and Contact Duration	Functions Performed
Aveta Disposable Hysteroscope	Sterile (EO), single use, used in the sterile field. Tyvek/Film Pouch	Polymers (PVC, ABS); Stainless Steel, direct patient contact for limited duration.	• Visualization of uterine cavity. • Provides conduits/lumens for inflow, outflow. • Provides conduit for mechanical Resecting Device for operative hysteroscopy. • Provides controls to the user to record images. • Provides controls to the user to perform image transfer
Aveta Controller (accessory)	Non-sterile, reusable, used outside the sterile field	No patient contact	• Camera, light, image processing and image storing.

V. Indications for Use

The indications for use of the modified Aveta System is a subset of the indications for use of the predicate Aveta System.

Comparison of Indications for Use

Device	Indications For Use
Aveta Disposable Hysteroscope (Subject Device)	The Aveta Disposable Hysteroscope is used to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.
Aveta System (Predicate) (K190372)	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.

This difference does not represent a new intended use.

VI. Comparison of Technological Characteristics with the Predicate Device

The subject Aveta Disposable Hysteroscope and the cleared Aveta Disposable Hysteroscope (cleared as a component of Aveta System K190372) have similar technological characteristics in terms of basic operating principle and basic design features with minor differences in compatible fluid sources and software of the Aveta Controller. The different technological characteristics of the subject devices do not raise different types of safety and effectiveness questions. The table below compares the subject device with the predicate device.

Attribute	Subject Device	PREDICATE Device
510k#	**K192100**	**K190372**
Manufacturer:	**Meditrina Inc.**	**Meditrina Inc.**
Device Names	**Aveta Disposable Hysteroscope**	**Aveta System**
Class:	**II**	**II**
Regulation Name:	**Hysteroscope and Accessories**	**Hysteroscope and Accessories / Hysteroscopic Insufflator**
Regulation Number:	**884.1690**	**884.1690 / 884.1700**
Product Code:	**HIH**	**HIH / HIG**
Intended Use:	Intended to permit viewing of the cervical canal and the uterine cavity.	Intended for the distention and visualization of the cervical canal and the uterine cavity and for endoscopic resection and removal of tissue chips via suction while monitoring volume differential between the irrigation fluid flowing into and out of the uterus.
Indications for Use:	The Aveta Disposable Hysteroscope is used to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.	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.
Materials of Construction:	Stainless Steel, ABS, Silicone elastomer, PVC, Polycarbonate	Stainless Steel, ABS, Silicone elastomer, PVC, Polycarbonate
Working Length:	224mm	224mm
Outer Diameter:	5.5mm	5.5mm
Working Channel Diameter:	3.5mm	3.5mm
Working Channel Closure:	Silicone valve	Silicone valve
Recommended Light Source:	Integrated LED	Integrated LED
Focal Length:	5 to 25mm	5 to 25mm
Working Distance:	10mm	10mm
Field of View:	90°	90°
Direction of View:	0°	0°
Optics	Fixed focus lens with CMOS sensor	Fixed focus lens with CMOS sensor

Attribute	Subject Device	PREDICATE Device
510k#	**K192100**	**K190372**
Manufacturer:	**Meditrina Inc.**	**Meditrina Inc.**
Device Names	**Aveta Disposable Hysteroscope**	**Aveta System**
Resolution @ Working Distance:	3.4 lp/mm at 25mm Working Distance	3.4 lp/mm at 25mm Working Distance
Image Processing:	Image generated by the CMOS sensor in Aveta Disposable Hysteroscope is processed and sent to Aveta Controller for further processing and displayed on a monitor	Image generated by the CMOS sensor in Aveta Disposable Hysteroscope is processed and sent to Aveta Controller for further processing and displayed on a monitor
How provided:	Sterile, single-use	Sterile, single-use
Sterilization Method:	Ethylene oxide gas	Ethylene oxide gas
SAL:	10^{-6}	10^{-6}
Fluid Management System:	• Use with gravity fed pressurized saline bag. • Use with The Aveta Fluid Management System cleared in K190372.	Used in combination with Aveta Fluid Management System
Tissue Resection:	• Used in combination with Aveta Disposable Resecting Device cleared in K190372	Used in combination with Aveta Disposable Resecting Device

The differences outlined above were evaluated to demonstrate safety and effectiveness of the Aveta Disposable Hysteroscope.

VII. Non-Clinical Performance Testing

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

- Software verification
- Simulated Use with gravity fed pressurized saline bag (Regulation of cavity pressure was demonstrated in a model uterine system, flow rate tests and tissue resection) was performed utilizing the Aveta Disposable Hysteroscope. Results demonstrate the subject device met specifications.

VIII. Conclusions

The results of the non-clinical testing described above demonstrate that the subject device is as safe and effective as the predicate device and support the subject device is substantially equivalent to the predicate device.