May 26, 2022

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

Re: K213171
Trade/Device Name: Aveta System, Aveta Disposable Hysteroscope (Pearl/Opal/Coral), Aveta Disposable Cystoscope (Coral)
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: II
Product Code: HIH, HIG, FAJ
Dated: April 21, 2022
Received: April 25, 2022

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,

Jason R. Roberts, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213171

Device Name
Aveta System, Aveta Disposable Hysteroscope (Pearl/Opal/Coral), Aveta Disposable Cystoscope (Coral)

Indications for Use *(Describe)*

AVETA SYSTEM:

Hysteroscopy:

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.

Cystoscopy:

The Aveta System is intended for use in endoscopic access to and examination of the lower urinary tract, including the bladder. When combined with accessory instruments, the system allows the user to perform various diagnostic and therapeutic procedures.

AVETA DISPOSABLE HYSTEROSCOPE (Pearl/Opal/Coral):

The Aveta Disposable Hysteroscope (Pearl/Opal/Coral) is intended to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

AVETA DISPOSABLE CYSTOSCOPE (Coral):

The Aveta Disposable Cystoscope (Coral) is intended for use in endoscopic access to and examination of the lower urinary tract, including the bladder. When combined with accessory instruments, the Cystoscope allows the user to perform various diagnostic and therapeutic 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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K213171 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 **Email:** csabat@hermesinnovations.com **Phone:** 415-215-7233 **Fax:** 408-418-4815
Date Prepared:	25 May 2022

II. Product Classification

Device Name:	Aveta System, Aveta Disposable Hysteroscope (Pearl/Opal/Coral), Aveta Disposable Cystoscope (Coral)

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

III. Predicate Device Information

Predicate Devices	Manufacturer	Predicate Device Names	510(k)#	Clearance Date
PREDICATE DEVICE	Meditrina, Inc.	Aveta System	K190372	May 16, 2019
Reference Device	UVision360, Inc.	Luminelle DTx Hysteroscopy System	K181909	August 16, 2018

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 intended cavity for the purpose of performing diagnostic and operative procedures (hysteroscopy and cystoscopy). 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 cavity. The Controller

provides continuous monitoring of the cavity pressure to the set pressure. For hysteroscopy, it also monitors the volume differential between saline inflow and outflow from the uterus (fluid deficit). The Controller connects to a sterile, single use disposable Scope (available in various configurations, see below) that allows visualization of the cavity and displays the images obtained from the Scope on a standard monitor. For operative hysteroscopy procedures, the Aveta System includes sterile, mechanical Disposable Resecting Device (available in various configurations, see below) powered by an integrated motor in the device handset or by use of an external Resecting Handset (available in two configurations, as a disposable device or a reusable device). The resecting device is inserted through the working channel of the sterile hysteroscope to resect the target tissue/pathology. For cystoscopy, when combined with accessory instruments the cystoscope is used for diagnostic and therapeutic procedures.

Table 1. Aveta System Components

Aveta System Component	Functions Performed
Aveta Controller and Footswitch	• Displays image/video and procedural information on external monitor. • Image / video processing / storing of the images. • Enables visualization functions of the Hysteroscope / Cystoscope. • Fluid Management with irrigation and aspiration functions. • Controls saline inflow and outflow for distention of the uterine cavity or lower urinary tract with the bladder for visualization. • Monitors and maintains intrauterine pressure or lover urinary tract cavity pressure to set pressure. • Monitors volume differential (fluid deficit for hysteroscopy). • Provides ON/OFF function of the Resecting Device. • Provides power to the Resecting Handsets, Disposable Resecting Devices with Handsets for oscillation at a preset speed for mechanical resection function of Disposable Resecting Device. • Provides power to the Drape Pump.
Aveta Hysteroscope/Aveta Cystoscope • Aveta Pearl Disposable Hysteroscope • Aveta Coral Disposable Hysteroscope • Aveta Opal Disposable Hysteroscope • Aveta Coral Disposable Cystoscope Collectively, they are called Aveta Disposable Scope or Endoscope.	• Hysteroscope: Visualization of cervical canal and uterine cavity • Cystoscope: Visualization of the lower urinary tract including the bladder • Provides conduits/lumens for fluid inflow and outflow • Provides conduit (working channel) for operative instruments for operative procedures • Provides user interface for intrauterine or urethral cavity set pressure and fluid deficit limit adjustments (for hysteroscopy), flush, and recording of images
Aveta Fluid Management Accessory	• Provides membrane in fluid inflow line to enable intrauterine or urethral cavity pressure monitoring/control using pressure transducer in Controller • Provides conduits for irrigation of saline and aspiration of waste. • Provides FMA Cassette with tubing for peristaltic pump functions of Aveta Controller.

Aveta System Component	Functions Performed
Aveta Disposable Resecting Device: • Aveta Wave+ Disposable Resecting Device, 3.9mm (DRD-Wave+) • Aveta Max Disposable Resecting Device, 3.9mm (DRD-Max) • Aveta Disposable Resecting Device, 3.9 (DRD-3.9) • Aveta Flex Disposable Resecting Device, 2.9mm (DRD-Flex) • Aveta Smol Disposable Resecting Device, 2.9mm (DRD-Smol) • Aveta Disposable Resecting Device, 2.9 and (DRD-2.9) • Aveta Auto Disposable Resecting Device (AUTO)	• Mechanically resects and removes tissue under suction o DRD-2.9 and DRD-3.9 require use of DRH or RRH for oscillation of resection tip o DRD-Wave+, DRD-Max, DRD-Flex, DRD-Smol, AUTO include motor in the device handle to oscillate resection tip o The motor in the device handle for AUTO also provides suction by peristaltic action and is only for use with the pressurized saline bag
Aveta Disposable Resecting Handset (DRH)	• Includes motor for oscillation of resection tip (used with DRD-2.9 and DRD-3.9)
Aveta Reusable Resecting Handset (RRH)	• Includes motor for oscillation of resection tip (used with DRD-2.9 and DRD-3.9)
Additional Aveta System Components / Accessories • Waste Management Accessory • Waste Bag (6L) • Aveta Reusable Cable, Opal • Roll Stand with Drape Pump • Monitor	• Collects tissue for pathology and stores the outflow fluid waste and collects fluid from the patient's under-buttocks drape. • Part of Waste Management Accessory. • Provides connection from the hysteroscope pigtail outside the sterile field to the Controller. • Roll Stand mounts the monitor and Controller for the system Drape Pump transfers collected waste fluid from drape to Waste Bag. • Commercially available surgical monitor. Displays image, procedural parameters and notifications.

V. Indications for Use

There is no difference in the indications for use for the Aveta System (subject device) when compared to the combined indications of the predicate system components.

Comparison of Indications for Use

Device	Indications For Use
Aveta System (Subject Device)	AVETA SYSTEM: Hysteroscopy: 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. Cystoscopy: The Aveta System is intended for use in endoscopic access to and examination of the lower urinary tract, including the bladder. When combined with accessory instruments, the system allows the user to perform various diagnostic and therapeutic procedures.
Aveta Disposable Hysteroscope (Subject Device)	AVETA DISPOSABLE HYSTEROSCOPE (Pearl/Opal/Coral): The Aveta Disposable Hysteroscope (Pearl/Opal/Coral) is intended to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.
Aveta Disposable Cystoscope (Subject Device)	AVETA DISPOSABLE CYSTOSCOPE (Coral): The Aveta Disposable Cystoscope (Coral) is intended for use in endoscopic access to and examination of the lower urinary tract, including the bladder. When combined with accessory instruments, the Cystoscope allows the user to perform various diagnostic and therapeutic procedures.
Aveta System (Predicate Device – 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.
UVision360 Luminelle DTx Hysteroscopy System (Reference Device – K181909)	Hysteroscopy: The LUMINELLE DTx Hysteroscopy System is used to permit direct viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures. Note: Hysteroscopes are used as tools to access the uterine cavity and are not, in and of themselves, a method of surgery. Generally recognized indications for diagnostic hysteroscopy include: • Abnormal bleeding • Infertility and pregnancy wastage • Evaluation of abnormal hysterosalpingogram • Intrauterine foreign body • Amenorrhea • Pelvic pain Generally recognized indications for operative hysteroscopy include: • Directed endometrial biopsy • Polypectomy • Submucous myomectomy • Transection of intrauterine adhesions • Transection of intrauterine septa

Device	Indications For Use
	• Endometrial ablation Cystoscopy: The LUMINELLE DTx Hysteroscopy System is intended for use in endoscopic access to and examination of the lower urinary tract, including the bladder. When combined with accessory instruments, the System allows the user to perform various diagnostic and therapeutic procedures.

The indications for use for the subject Aveta System is identical to the reference device and has minor difference to the cleared Aveta System.

VI. Comparison of Technological Characteristics with the Predicate Device

Aveta System and the predicate system have the same or 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	**PRIMARY Predicate Device**	**Reference Device**		
510k#	**K213171**	**K190372**	**K191958**	**K192100**	**K181909**
Manufacturer:	**Meditrina Inc.**	**Meditrina, Inc.**			**UVision360**
Device Names	**Aveta System Aveta Hysteroscope Aveta Cystoscope**	**Aveta System**	**Aveta System**	**Aveta Disposable Hysteroscope**	**Luminelle DTx Hysteroscopy System**
CONTROLLER FUNCTIONS					
Hysteroscope Functions					
Visualization and Image Processing	CMOS sensor, and light source in Endoscope with image processing by the Controller	CMOS sensor, and light source in Hysteroscope with image processing by the Controller	N/A (Used in combination with hysteroscope and accessories of the commercial 3rd party hysteroscope)	CMOS sensor, and light source in Hysteroscope with image processing by the Controller	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Viewing Functions	Controller connects to a commercially available external Monitor and displays image from the cavity, plays tone, displays cavity pressure, fluid deficit with graphical user interface.	Controller connects to a commercially available external Monitor and displays image from the cavity, plays tone, displays cavity pressure, fluid deficit with graphical user interface.	Controller connects to a commercially available external Monitor and plays tone, displays cavity pressure, fluid deficit with graphical user interface but doesn't display image from cavity.	Controller connects to a commercially available external Monitor and displays image from the cavity and plays tone.	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Fluid Management Functions					
Fluid Distension	Continuous flow of saline/fluid	Continuous flow of saline/fluid	YES	N/A	N/A: All technical information for the SE comparison will be taken from the primary predicate.

	Subject Device	PRIMARY Predicate Device	Reference Device		
510k#	**K213171**	**K190372**	**K191958**	**K192100**	**K181909**
Manufacturer:	**Meditrina Inc.**	**Meditrina, Inc.**			**UVision360**
Device Names	**Aveta System Aveta Hysteroscope Aveta Cystoscope**	**Aveta System**	**Aveta System**	**Aveta Disposable Hysteroscope**	**Luminelle DTx Hysteroscopy System**
Irrigation for Distension	Peristaltic pump with dual pressure sensors for irrigation of fluids	Peristaltic pump with dual pressure sensors for irrigation of fluids	Peristaltic pump with dual pressure sensors for irrigation of fluids	N/A	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Aspiration of bodily fluids and tissue	Integrated Peristaltic pump for aspiration.	Integrated Peristaltic pump for aspiration.	Integrated Peristaltic pump for aspiration.	N/A	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Intrauterine Pressure Measurements	Obtains two independent, intrauterine pressure measurement by sensing pressure of the irrigation tube	Obtains two independent, intrauterine pressure measurement by sensing pressure of the irrigation tube	Obtains two independent, intrauterine pressure measurement by sensing pressure of the irrigation tube	N/A	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Set Pressure Range	Hysteroscopy: 30-120 mmHg Cystoscopy: 30-60mmHg	Hysteroscopy: 30-120 mmHg Cystoscopy: N/A	Hysteroscopy: 30-120 mmHg Cystoscopy: N/A	N/A	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Set Pressure User Adjustments	Allows user to increase/decrease the set pressure	Allows user to increase/decrease the set pressure	Allows user to increase/decrease the set pressure	N/A	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Pressure Relief for overpressure risk mitigation	Hysteroscopy: Reverse rotation of irrigation peristaltic pump at 150mmHg Cystoscopy: Reverse rotation of irrigation peristaltic pump at 75mmHg	Hysteroscopy: Reverse rotation of irrigation peristaltic pump at 150mmHg Cystoscopy: N/A	Hysteroscopy: Reverse rotation of irrigation peristaltic pump at 150mmHg Cystoscopy: N/A	N/A	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Fluid Deficit Measurement	YES	YES	YES	N/A	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Flow Rate	180-500 mL/min preset fixed flow rates	180-500 mL/min preset fixed flow rates	180-500 mL/min preset fixed flow rates	N/A	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Mechanical Resection Functions					

	Subject Device	PRIMARY Predicate Device	Reference Device		
510k#	**K213171**	**K190372**	**K191958**	**K192100**	**K181909**
Manufacturer:	**Meditrina Inc.**	**Meditrina, Inc.**			**UVision360**
Device Names	**Aveta System Aveta Hysteroscope Aveta Cystoscope**	**Aveta System**	**Aveta System**	**Aveta Disposable Hysteroscope**	**Luminelle DTx Hysteroscopy System**
Mechanical Resecting Device	Connects to the Resecting Handset by an electrical connection to provide motor control with a preset fixed motor rotation/oscillation speed.	Connects to the Resecting Handle by an electrical connection to provide motor control with a user adjustable motor oscillation speed.	Connects to the Resecting Handle by an electrical connection to provide motor control with a user adjustable motor oscillation speed.	Connects to the Resecting Handle by an electrical connection to provide motor control with a user adjustable motor oscillation speed.	N/A: All technical information for the SE comparison will be taken from the primary predicate.
SCOPE					
Disposable Hysteroscope/Cystoscope					
Irrigation and Aspiration Lumens	Independent sterile saline irrigation and aspiration lumens	Independent sterile saline irrigation and aspiration lumens	N/A	Independent sterile saline irrigation and aspiration lumens	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Insertion OD	Pearl Hysteroscope: 5.7mm Coral Hysteroscope: 4.6mm Opal Hysteroscope: 4.6mm Coral Cystoscope: 4.6mm	5.5 mm	N/A	5.5 mm	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Working Length	Pearl Hysteroscope: 216mm Coral Hysteroscope 206mm Opal Hysteroscope 206mm Coral Cystoscope: 206mm	224mm	N/A	224mm	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Illumination	LEDs (Light Emitting Diode)	LEDs (Light Emitting Diode)	N/A	LEDs (Light Emitting Diode)	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Working Channel	Pearl Hysteroscope: 4.0mm Coral Hysteroscope: 3.0mm Opal Hysteroscope: 3.0mm Coral Cystoscope: 3.0mm	3.5mm	N/A	3.5mm	N/A: All technical information for the SE comparison will be taken from the primary predicate.

	Subject Device	PRIMARY Predicate Device	Reference Device		
510k#	**K213171**	**K190372**	**K191958**	**K192100**	**K181909**
Manufacturer:	**Meditrina Inc.**	**Meditrina, Inc.**			**UVision360**
Device Names	**Aveta System Aveta Hysteroscope Aveta Cystoscope**	**Aveta System**	**Aveta System**	**Aveta Disposable Hysteroscope**	**Luminelle DTx Hysteroscopy System**
Camera	Digital CMOS Camera	Digital CMOS Camera	N/A	Digital CMOS Camera	N/A: All technical information for the SE comparison will be taken from the primary predicate.
RESECTION SYSTEM					
Disposable Resecting Device (DRD)					
Cutting Window	DRD-Wave+: 8mm DRD-Max: 11mm DRD-3.9: 10mm DRD-Flex: 7mm DRD-Smol: 7mm DRD-2.9: 7mm AUTO: 8mm	8 mm	N/A	N/A	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Blade Material	Stainless steel	Stainless steel	N/A	N/A	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Working Length	DRD-Wave+: 339mm DRD-Max: 339mm DRD-3.9: 328mm DRD-Flex: 339mm DRD-Smol: 339mm DRD-2.9: 328mm AUTO: 318mm	328 mm	N/A	N/A	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Insertion OD	DRD-Wave+: 3.9mm DRD-Max: 3.9mm DRD-3.9: 3.9mm DRD-Flex: 2.9mm DRD-Smol: 2.9mm DRD-2.9: 2.9mm AUTO: 2.9mm	3.4 mm	N/A	N/A	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Rotational Speed	3000RPM	2000RPM	N/A	N/A	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Suction Assisted Resection?	YES	YES	N/A	N/A	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Disposable (Sterile) and Reusable (Steam Sterilizable) Resecting Handset					

	Subject Device	PRIMARY Predicate Device	Reference Device		
510k#	**K213171**	**K190372**	**K191958**	**K192100**	**K181909**
Manufacturer:	**Meditrina Inc.**	**Meditrina, Inc.**			**UVision360**
Device Names	**Aveta System Aveta Hysteroscope Aveta Cystoscope**	**Aveta System**	**Aveta System**	**Aveta Disposable Hysteroscope**	**Luminelle DTx Hysteroscopy System**
Resection Mechanism	Mechanical	Mechanical	N/A	N/A	N/A: All technical information for the SE comparison will be taken from the primary predicate.
User Controls	Handset Controls	Handset Controls	N/A	N/A	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Mechanical Connection	Locks Disposable Resecting Device	Locks Disposable Resecting Device	N/A	N/A	N/A: All technical information for the SE comparison will be taken from the primary predicate.
Rotational Speed	2000 RPM (pre-set – not user adjustable)	2000 RPM (pre-set – not user adjustable)	N/A	N/A	N/A: All technical information for the SE comparison will be taken from the primary predicate.

The differences outlined were evaluated through performance testing to demonstrate safety and effectiveness of the Aveta System.

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 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 per approved test protocols which included:
  - Integrity: System withstands operating pressures
  - Dimensional Inspection and Testing
  - Functional Testing for all components of the system
    - Controller
      - Weight accuracy
      - Pressure accuracy and control
      - Suction
      - Fluid Deficit
    - Scopes
      - Optical testing
      - Leak and flow rate
      - Maximum LED Tip Temperature
    - Resecting Devices
      - Motor/Oscillation speed

-
  - Fluid Management Accessory
    - Leak and flow rate
- Simulated Use: Tissue resection, regulation of cavity pressure, imaging
- Comparative testing to predicate for pressure control, fluid deficit, fluid control and durability.
- Biocompatibility Evaluation per ISO 10993-1 (No new testing performed. No change in materials from the cleared device).
- Sterilization Validation per ISO 11135 and ISO 11137-1/-2/-3.
- Packaging Validation per ASTM D4169.
- Accelerated Aging per ASTM F1980
- Electrical Safety & EMC: In accordance with IEC 60601-1:2005, IEC 60601-1-2:2014 and IEC 60601-2-18:2009.

VIII. Conclusions

The modified Aveta System, Aveta Hysteroscope and the Aveta Cystoscope are substantially equivalent to the cleared predicate i.e., Aveta System based on the same intended use, technological characteristics and principles of operation. Bench testing supports the subject device is as safe and effective for its proposed indications for use as the predicate device.