August 21, 2023

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

Re: K223813
Trade/Device Name: Aveta System 2.0
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: II
Product Code: HIH, HIG, FAJ
Dated: July 28, 2023
Received: July 31, 2023

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 Roberts -S

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)*
K223813

Device Name
Aveta System 2.0

Indications for Use *(Describe)*

AVETA SYSTEM 2.0:
USING BIPOLAR RF DEVICE:
-Hysteroscopy:
Aveta System 2.0 for Hysteroscopy: The Aveta System 2.0 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, remove and coagulate tissue such as submucous myomas, endometrial polyps, adhesions and retained products of conception using a bipolar resecting device.
USING MECHANICAL RESECTING DEVICES:
-Hysteroscopy:
The Aveta System 2.0 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 2.0 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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K223813 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:	16 August 2023

II. Product Classification

Device Name:	Aveta System 2.0

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

III. Predicate Device Information

Predicate Devices	Manufacturer	Predicate Device Names	510(k)#	Clearance Date
Predicate #1 **(PRIMARY PREDICATE)**	Meditrina, Inc.	Aveta System, Aveta Disposable Hysteroscope (Pearl/Opal/Coral), Aveta Disposable Cystoscope (Coral)	K213171	May 26, 2022
Predicate #2 (Secondary Predicate)	Gynecare, Inc.	Scuba (Gynecare Versapoint) System	K962482	November 1, 1996

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

IV. Device Description

The Aveta System 2.0 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 2.0 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. Controller 2.0 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). Controller 2.0 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. The Controller 2.0 provides bipolar Radiofrequency (RF) energy to deliver to the Aveta Glo Disposable RF Device for CUT and COAG functions. For operative hysteroscopy procedures, the Aveta System also includes sterile, mechanical Disposable Resecting Device (available in various configurations, see below) powered by an integrated motor in the device handset. The resecting device (RF or mechanical) 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 2.0 Components and their Functions

Aveta System 2.0 Component	Functions Performed
Aveta Controller 2.0 and Footswitch (includes single pedal or dual pedal 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 Disposable Resecting Devices for oscillation at a preset speed for mechanical resection function of Disposable Resecting Device. • Provides power to the Drape Pump. • Provides bi-polar RF energy to the tissue via the GLO Disposable RF Device.
Aveta Disposable Hysteroscope (Coral, Pearl and Opal) and Aveta Coral Disposable Cystoscope Collectively, they are called Aveta Disposable Scope or just 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 • For Coral and Pearl hysteroscopes, 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 2.0.
Aveta Disposable Resecting Devices (DRDH-Wave+, DRDH-Flex, DRDH-Smol, DRDH-AUTO and DRDH-AUTO-5Fr)	• Mechanically resects and removes tissue under suction o DRDH-Wave+, DRDH-Flex, DRDH-Smol, AUTO and AUTO-5Fr includes motor in the device handle to oscillate resection tip for the DRDHs and to rotate the resection tip for Auto and Auto-5Fr. o The motor in the device handle for AUTO and AUTO-5Fr also provides suction by peristaltic action and are only for use with the pressurized saline bag.
Aveta Glo Disposable RF Device, 7Fr.	• Performs bipolar resection (RF CUT) and removes tissue under suction and coagulates (RF COAG) tissue to reduce or eliminate bleeding and improve visibility.
Additional Aveta System Components / Accessories • Waste Management Accessory • Waste Bag (6L) • Roll Stand with Drape Pump • Monitor • Reusable Cable, Opal	 • Collects tissue for pathology, stores the outflow fluid waste, collects fluid from the patient's under-buttocks drape • Part of Waste Management Accessory • 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 • Connects the Opal Hysteroscope to the Controller

V. Indications for Use

There is no difference in the indications for use for the Aveta System 2.0 (subject device) when compared to the indications of the predicate devices.

Comparison of Indications for Use

Device	Indications For Use
Aveta System 2.0 (Subject Device)	AVETA SYSTEM 2.0: USING BIPOLAR RF DEVICE: -Hysteroscopy: Aveta System 2.0 for Hysteroscopy: The Aveta System 2.0 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, remove and coagulate tissue such as submucous myomas, endometrial polyps, adhesions and retained products of conception using a bipolar resecting device. USING MECHANICAL RESECTING DEVICES: -Hysteroscopy: The Aveta System 2.0 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 2.0 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.
Aveta System (Predicate Device #1)	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.
Scuba (Gynecare Versapoint) System (Predicate Device #2)	The Scuba (Gynecare Versapoint) System is intended for tissue cutting, vaporization and desiccation as required or encountered in gynecologic hysteroscopic electrosurgical procedures for excision of intrauterine myomas and polyps, lysis of intrauterine adhesions, and excision of uterine septa.

The indications for use for the subject Aveta System 2.0 is similar to the indications for use for primary Predicate #1 (Aveta System) and Predicate #2 (Scuba (Gynecare Versapoint) System)).

VI. Comparison of Technological Characteristics with the Predicate Device

Aveta System 2.0 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 2.0 with Predicate Devices

	Subject Device	PREDICATE #1 Primary Predicate	PREDICATE #2 Secondary Predicate
510k#	**K223813**	**K213171**	**K962482**
Manufacturer:	**Meditrina Inc.**	**Meditrina Inc.**	**Gynecare, Inc.**
Device Names	**Aveta System 2.0**	**Aveta System** **Aveta Hysteroscope** **Aveta Cystoscope**	**Scuba (Gynecare Versapoint) System**
CONTROLLER FUNCTIONS			
Hysteroscope /Cystoscope Functions			
Visualization and Image Processing	CMOS sensor, and light source in Endoscope with image processing by the Controller	CMOS sensor, and light source in Endoscope with image processing by the Controller	N/A
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.	NA
Fluid Management Functions			
Fluid Distension	Continuous flow of saline/fluid	Continuous flow of saline/fluid	NA
Irrigation for Distension	Peristaltic pump with dual pressure sensors for irrigation of fluids	Peristaltic pump with dual pressure sensors for irrigation of fluids	NA
Aspiration of bodily fluids and tissue	Integrated Peristaltic pump for aspiration.	Integrated Peristaltic pump for aspiration.	NA
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	NA
Set Pressure Range	Hysteroscopy: 30-120 mmHg Cystoscopy: 30-60mmHg	Hysteroscopy: 30-120 mmHg Cystoscopy: 30-60mmHg	NA
Set Pressure User Adjustments	Allows user to increase/decrease the set pressure	Allows user to increase/decrease the set pressure	NA
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: Reverse rotation of irrigation peristaltic pump at 75mmHg	NA
Fluid Deficit Measurement	YES	YES	NA
Flow Rate	180-500 mL/min preset fixed flow rates	180-500 mL/min preset fixed flow rates	NA

	Subject Device	PREDICATE #1 Primary Predicate	PREDICATE #2 Secondary Predicate
510k#	**K223813**	**K213171**	**K962482**
Manufacturer:	**Meditrina Inc.**	**Meditrina Inc.**	**Gynecare, Inc.**
Device Names	**Aveta System 2.0**	**Aveta System** **Aveta Hysteroscope** **Aveta Cystoscope**	**Scuba (Gynecare Versapoint) System**
Resection Functions			
Mechanical Resecting Device	Connects to the Controller 2.0 by an electrical connection to provide motor control with a preset fixed motor rotation/oscillation speed.	Connects to the Controller by an electrical connection to provide motor control with a preset fixed motor rotation/oscillation speed.	N/A
Bipolar RF Device	Cut and Coagulate tissue when active electrode is extended and powered by controller, only when activated by the dual footswitch	NA	Cut and Coagulate Uterine tissue when active electrode is extended and powered by controller
RF CUT, COAG Power Waveform and frequency	Bipolar CUT 110 W @ 150Ω COAG 55W @ 150Ω quasi sinusoidal waveform 205 kHz	N/A	Bipolar CUT 200W @ 160Ω COAG 125W @ 160Ω variable amplitude sinusoid waveform varying between 340kHz and 450kHz
DISPOSABLE HYSTEROSCOPE/CYSTOSCOPE			
Irrigation and Aspiration Lumens	Independent sterile saline irrigation and aspiration lumens	Independent sterile saline irrigation and aspiration lumens	NA
Insertion OD	Pearl Hysteroscope: 5.7mm Coral Hysteroscope: 4.6mm Opal Hysteroscope: 4.6mm Coral Cystoscope: 4.6mm	Pearl Hysteroscope: 5.7mm Coral Hysteroscope: 4.6mm Opal Hysteroscope: 4.6mm Coral Cystoscope: 4.6mm	NA
Working Length	Pearl Hysteroscope: 216mm Coral Hysteroscope: 206mm Opal Hysteroscope: 206mm Coral Cystoscope: 206mm	Pearl Hysteroscope: 216mm Coral Hysteroscope: 206mm Opal Hysteroscope: 206mm Coral Cystoscope: 206mm	NA
Illumination	LEDs (Light Emitting Diode)	LEDs (Light Emitting Diode)	NA
Working Channel	Pearl Hysteroscope: 4.0mm Coral Hysteroscope: 3.0mm Opal Hysteroscope: 3.0mm Coral Cystoscope: 3.0mm	Pearl Hysteroscope: 4.0mm Coral Hysteroscope: 3.0mm Opal Hysteroscope: 3.0mm Coral Cystoscope: 3.0mm	NA
Camera	Digital CMOS Camera	Digital CMOS Camera	NA
RESECTION SYSTEM			
Disposable Resecting Devices (DRD, DRDH, AUTO, AUTO-5Fr), Disposable RF Device (GLO)			
Cutting Window	DRDH-Wave+: 8mm DRDH-Flex: 7mm DRDH-Smol: 7mm AUTO: 8mm AUTO-5Fr: 8mm GLO: N/A (no cutting window)	DRDH-Wave+: 8mm DRDH-Max: 11mm DRD-3.9: 10mm DRDH-Flex: 7mm DRDH-Smol: 7mm DRD-2.9: 7mm AUTO: 8mm	NA
Tip / Electrode Material	Stainless steel	Stainless steel	Metal (Gynecare Proprietary)

	Subject Device	PREDICATE #1 Primary Predicate	PREDICATE #2 Secondary Predicate
510k#	**K223813**	**K213171**	**K962482**
Manufacturer:	**Meditrina Inc.**	**Meditrina Inc.**	**Gynecare, Inc.**
Device Names	**Aveta System 2.0**	**Aveta System Aveta Hysteroscope Aveta Cystoscope**	**Scuba (Gynecare Versapoint) System**
Working Length	DRDH-Wave+: 339mm DRDH-Flex: 339mm DRDH-Smol: 339mm AUTO: 318mm AUTO-5Fr: 318 mm GLO: 339mm	DRDH-Wave+: 339mm DRDH-Max: 339mm DRD-3.9: 328mm DRDH-Flex: 339mm DRDH-Smol: 339mm DRD-2.9: 328mm AUTO: 318mm	Twizzle Tip: 360mm
Insertion OD	DRDH-Wave+: 3.9mm DRDH-Flex: 2.9mm DRDH-Smol: 2.9mm AUTO: 2.9mm AUTO-5Fr: 1.67mm GLO: 2.33mm	DRDH-Wave+: 3.9mm DRDH-Max: 3.9mm DRD-3.9: 3.9mm DRDH-Flex: 2.9mm DRDH-Smol: 2.9mm DRD-2.9: 2.9mm AUTO: 2.9mm	NA
Rotational Speed	DRDH-Wave+: 5,000 rpm DRDH-Flex: 10,000 rpm DRDH-Smol: 3,000 rpm AUTO: 3,000 rpm AUTO-5Fr: 3,000 rpm	DRDH-Wave+: 3,000rpm DRDH-Max: 3,000rpm DRD-3.9: 3,000rpm DRDH-Flex: 3,000rpm DRDH-Smol: 3,000rpm DRD-2.9: 3,000rpm AUTO: 3,000rpm	NA
Suction Assisted Resection	YES	YES	NA

The differences outlined were evaluated through performance testing to demonstrate safety and effectiveness of the Aveta System 2.0.

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
  - Functional Testing: Cut and coagulation, aspiration, irrigation, pressure control
  - Dimensional Inspection and Testing
  - Functional Testing for all components of the system
    - Controller
      - Weight accuracy
      - Pressure accuracy and control
      - Suction
    - Mechanical Resecting Devices
      - Motor speed
      - Oscillation
    - RF Device
      - CUT
      - COAG

- Simulated Use: Tissue resection, regulation of cavity pressure, imaging, CUT, COAG
- Comparative Testing
- Biocompatibility Evaluation per ISO 10993-1 and testing for the Bipolar Resecting Device (GLO). No new testing performed on other components. 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 Edition 3.1(or AMD2:2020), IEC 60601-1-2: Edition 4.1(or AMD1:2020), IEC 60601-2-18 and IEC 62304 Edition 1.1:2015-06

VIII. Conclusions

The Aveta System 2.0, is substantially equivalent to the cleared predicates based on the same intended use, technological characteristics and principles of operation. Bench testing supports the subject device is as safe and effective as the predicate device for its proposed indications for use.