April 24, 2019

Corinth MedTech, Inc.
Sandeep Saboo
Vice President, Quality Assurance & Regulatory Affairs
1601 S. De Anza Blvd., Suite 200
Cupertino, CA 95014

Re: K190113
Trade/Device Name: Veloxion System
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: II
Product Code: HIH, HIG, GEI
Dated: January 22, 2019
Received: January 24, 2019

Dear Sandeep Saboo:

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,

Jason Roberts -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*
K190113

Device Name
Veloxion System

Indications for Use *(Describe)*
The Veloxion System is intended for intrauterine use by trained gynecologists for endoscopically controlled tissue chip resection and coagulation, and removal of intrauterine polyps and myomas via suction channel under continuous flow conditions following resection using a bipolar resectoscope. It is also intended to distend the uterus by filling with saline to facilitate viewing and to monitor the volume differential between fluid flowing into and out of the uterus.

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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Corinth MedTech, Inc.

Veloxion System
Traditional 510(k) Premarket Notification

K 190113 : 510(k) Summary

I. Submitter Information

Submitter name:	Corinth MedTech, Inc. 1601 S. De Anza Blvd, Suite 200 Cupertino, CA 95014
Contact person:	Sandeep Saboo Vice President, Regulatory Affairs and Quality Assurance Phone: (408) 996-2517 Fax: (408) 996-0621
Date Prepared:	21 January 2019

II. Product Classification

Device Name:	Veloxion System

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

III. Predicate Devices

The predicate device is the system comprised of the following legally marketed devices as used in combination to which substantial equivalence is claimed:

Primary Predicate: Veloxion System (cleared per K180752)
Predicate: Hysteroscope A22002A Olympus Corp. (cleared per K897003)

Predicate devices have not been a subject of a design related recall.

IV. Device Description

The Veloxion System consists of the following components:

- Veloxion Controller **(**with Integrated Fluid Control**)**
  - Footswitch
- Veloxion Resectoscope
- Veloxion Fluid Control Set
- Veloxion Video Control Unit
- Veloxion Roll Stand

The Veloxion System also includes the following Class I accessories for handling of waste collected from the patient (these items only handle waste after it is already outside the patient), which includes:

- Waste Management Tubing: To provide a conduit for transfer of aspirated fluids and tissue from the patient and from under the patient's buttocks drape
- Tissue Catch: For collection of gross resected tissue pieces for pathology.
- Waste Management Bags: To provide bags for final collection of outflow.

The Veloxion System provides bipolar resection and coagulation of intrauterine tissue, it distends the uterus by filling with saline, it provides pressure control of the intrauterine cavity for insufflation to facilitate viewing with the integrated hysteroscope and it monitors the fluid deficit (potential fluid absorbed by the patient's body) to the physician established limit. The components of Veloxion System perform the following functions:

- The Veloxion Controller provides bipolar radiofrequency outputs (for cut and coagulation) and fluid/pressure control through the use of two integrated peristaltic pumps, provides the user interface to establish the desired set pressure, monitors intracavitary pressure using dual independent pressure sensors mechanically connected to the Veloxion Fluid Control Set irrigation lumen. The software then monitors, controls and notifies the user when the limits are reached or when specific conditions are met.
- The Veloxion Resectoscope is a sterile single use hand held bipolar radiofrequency device configured to provide camera and light for visualization of the anatomy for the resection of tissue and aspiration of resected chips. Fluid inflow and aspiration of the resected chips are controlled by the Controller's peristaltic pumps.
- The Veloxion Fluid Control Set is a sterile single use device that provides conduits for fluid inflow, aspiration of resected tissue and fluids and a diaphragm (pressure membrane) that provides mechanism for the Controller to measure cavity pressure (through the irrigation lumen) during the procedure thereby facilitating the insufflation function.
- The Veloxion Video Control Unit provide control of the camera, light, display image to a commercially available monitor, stores image and video selected by the user from a session, and provides a USB connection for a USB Stick download of stored media by the user.
- The Veloxion Roll Stand enables monitoring of saline remaining in the saline bag and facilitates the fluid deficit function.

V. Indications for Use

There is no difference in the indications for use for the modified Veloxion System (subject device) when compared to the predicate device (cleared Veloxion System, per K180752)

Comparison of Indications for Use

Device	Indications For Use
Modified Veloxion System (Subject Device)	The Veloxion System is intended for intrauterine use by trained gynecologists for endoscopically controlled tissue chip resection and coagulation, and removal of intrauterine polyps and myomas via suction channel under continuous flow conditions following resection using a bipolar resectoscope. It is also intended to distend the uterus by filling with saline to facilitate viewing and to monitor the volume differential between fluid flowing into and out of the uterus.
Veloxion System K180752 (Predicate Device)	The Veloxion System is intended for intrauterine use by trained gynecologists for endoscopically controlled tissue chip resection and coagulation, and removal of intrauterine polyps and myomas via suction channel under continuous flow conditions following resection using a bipolar resecting device. It is also intended to distend the uterus by filling with saline to facilitate viewing with a hysteroscope and to monitor the volume differential between fluid flowing into and out of the uterus.

VI. Comparison of Technological Characteristics with the Predicate Device

The subject Veloxion System and the previously cleared Veloxion System (K180752) and Olympus Hysteroscope (K897003) have the same or similar technological characteristics (see Table 1 and Table 2) in terms of basic operating principle and basic design features with a key difference being that the subject Veloxion System includes a sterile, single use camera and light while the predicate uses a commercially available reusable endoscope.

Table 1: Comparison of subject Veloxion System and predicate Veloxion System:

Technological Characteristics	VELOXION SYSTEM (Subject)	VELOXION SYSTEM (Predicate)
Monopolar or Bipolar	Bipolar	Bipolar
Energy Type:	Radiofrequency, Bipolar	Radiofrequency, Bipolar
Optics:	Integrated, Sterile, 10° Endoscope	Compatible with reusable 30° marketed Endoscope
Set Fluid Deficit Range:	From 250 to 2500ml	From 250 to 2500ml
Fluid Deficit Rate ≥ 300ml/min notification to user?	YES	YES
Notification to user when Actual fluid deficit is 1000ml?	YES (no pause, notification only)	YES
Notification to user with pause when Actual fluid deficit is 2000ml?	YES	NO
Notification when Actual fluid deficit is within 250ml of Set Limit?	YES	YES
Device Stops when Set Limit or 2500ml is reached?	YES	YES
Set Pressure Range:	35 to 120mmHg	35 to 125mmHg
Positive Action to Increase Above 100mmHg:	YES	YES
Pressure Sensor:	Dual, independent sensing of cavity pressure	Dual, independent sensing of cavity pressure
Over-pressure condition detection:	YES	YES
Maximum Allowable Actual Cavity Pressure	135mmHg for 5 seconds	135mmHg for 5 seconds
Primary mitigation for risk of over-pressurization of uterus:	• Reverse rotation of irrigation wheel	• Reverse rotation of irrigation wheel
Ultimate mitigation for risk of over-pressurization of uterus if all designed mitigations are unsuccessful	• Non-defeatable, continuous notification tone • Notification displayed: **"Remove device from cavity. Check for Clog."**	• Non-defeatable, continuous notification tone • Notification displayed: • **"Remove device from cavity. Check for Clog."**
Continuous Flow? :	YES	YES
Irrigation fluid:	Saline	Saline
Maximum # of saline bag(s) hung on saline load cell:	Four (4)	One (1)
Load cells:	Separate load cells to weigh the saline bags and the waste bags	One load cell to weigh the combined saline and waste bag load
Pump?	Dual Pump (Irrigation, Aspiration)	Dual Pump (Irrigation, Aspiration)
Irrigation Flow Rate:	Programmed irrigation flow rate constant for each mode: Steady State = 100ml/min, Cut = 380ml/min, Coag = 100ml/min, ASPIRATE = 650ml/min	Programmed irrigation flow rate constant for each mode: Steady State = 100ml/min, Cut = 380ml/min, Coag = 100ml/min, ASPIRATE = 400ml/min
Suction for aspiration of waste from patient drape:	Facility Suction	Waste Accessory Pump
Able to Monitor saline remaining?:	YES	YES
Shaft OD (Sheath):	With Sheath Assembled: 25Fr (8.3mm)	With Sheath Assembled: 26Fr (8.6mm)
Working Length:	Sheath Working Length: 220mm	Sheath Working Length: 193mm

Technological Characteristics	VELOXION SYSTEM (Subject)	VELOXION SYSTEM (Predicate)
Electrode (Dimension/Material/ Insulation/Actuation):	OD: 0.019” Material: Tungsten (99.95% purity) Insulation: FEP Actuation: Linear Oscillating Loop	OD: 0.015” Material: Tungsten (99.95% purity) Insulation: FEP Actuation: Circumferential Oscillating Wire
How Supplied (Sterility):	Sterile, Single Use (Veloxion Resectoscope, Veloxion Fluid Control Set)	Sterile, Single Use (Veloxion Resecting Device Kit, Veloxion Fluid Control Set)

Table 2: Comparison of subject Veloxion System and predicate Olympus Hysteroscope:

Technological Characteristics	VELOXION SYSTEM (Subject)	Olympus Hysteroscope (K897003)
OD:	Inner Sheath: 6.5mm	4.0mm
Working Length:	220mm	280mm
DOV:	10°	30°
FOV:	85°	57°
Working Distance:	5 to 50mm	20mm
Light Source:	LED light	Xenon, Halogen, LED
Imaging:	Integrated CMOS sensor	External CCD camera
Total # Pixels:	160,000	Unknown
Pixels/mm^2:	160,000	Unknown
Active Area of CCD Chip:	714 µm x 707 µm	Unknown

The main technological differences between the subject Veloxion System and the predicate Veloxion System are the following:

- The subject Veloxion System includes a sterile, single-use camera and light system while the predicate Veloxion System uses a commercially available reusable Endoscope.
- The subject Veloxion System includes programmed flow rates that are slightly different than the predicate Veloxion System as a result of an integrated passive flow mechanism.

The differences outlined were evaluated through performance testing to demonstrate safety and effectiveness of the subject Veloxion 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
  - 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
  - Comparative visualization testing in a simulated model
  - Simulated Use: Tissue resection and spot coagulation, regulation of cavity pressure, imaging
  - Durability Testing: Electrode durability testing for tissue resection and coagulation.
  - Comparative testing to predicate for electrode durability, pressure control, fluid deficit, fluid control, resolution per ISO 8600-5, distortion and photobiologic safety per IEC 62471:2006.
  - Thermal effects evaluation.
  - Biocompatibility Testing per ISO 10993-1.
  - 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, IEC 60601-2-18:2009 and IEC 60601-2-2:2009.
  - Usability Testing: Use related risk evaluation

VIII. Conclusions

Based on the results of performance tests, the subject Veloxion System is considered to be substantially equivalent and as safe and effective as the predicate Veloxion System (K180752).