June 6, 2019

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

Re: K191335
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: May 15, 2019
Received: May 17, 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/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,

Sharon M. 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)*
K191335

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 and benign conditions requiring endometrial ablation 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K191335: 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:	5 June 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 Device

Predicate	Manufacturer	Predicate Device Names	510(k)#	Clearance Date
Primary Predicate	Corinth MedTech, Inc.	Veloxion System	**K190113**	April 24, 2019

Predicate device has not been the 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

When compared to the predicate, the subject device includes the addition of endometrial ablation to the indications for use. This difference in indications for use does not represent a new intended use.

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 and benign conditions requiring endometrial ablation 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 K190113 (Primary Predicate)	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.

VI. Comparison of Technological Characteristics with the Predicate Device

The subject Veloxion System has the same technological characteristics as the predicate device.

VII. Performance Data

Results of tests provided for the predicate were adequate to support the new indication.

VIII. Conclusions

The subject Veloxion System is as safe and effective as the predicate device.