June 13, 2019

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

Re: K191341
Trade/Device Name: Veloxion System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FJL, KQT, GEI
Dated: May 15, 2019
Received: May 20, 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,

for Glenn B. Bell, Ph.D.
Assistant Division 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)*
K191341

Device Name
Veloxion System

Indications for Use *(Describe)*
The Veloxion System is intended for use by trained urologists for endoscopically controlled tissue chip resection and coagulation, and removal of prostate adenomas and bladder tumors (TURBT) via suction channel under continuous flow conditions following resection using a bipolar resectoscope.

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."

K191341: 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:	14 May 2019

II. Product Classification

Device Name:	Veloxion System

Common Name:	Resectoscope	Subject Device
Regulation:	21 CFR 876.1500	
Regulation Name:	Endoscope and accessories	
Class:	II	
Product Code:	FJL	
Additional Product Codes:	KQT, 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:

Predicate	Manufacturer	Predicate Device Names	510(k)#	Clearance Date
Primary Predicate Predicate #1	Corinth MedTech, Inc.	Veloxion System	**K190099**	March 15, 2019
Predicate #2 (predicate system)	Richard Wolf Medical Instruments Corporation	S-Line Bipolar Resectoscope & ERBE ESU	**K062720**	March 22, 2007
Predicate #3 (predicate system)	Richard Wolf Medical Instruments Corporation	Resection Master & ERBE ESU	**K042523**	March 18, 2005
Predicate #4 (predicate system)	Corinth MedTech, Inc.	Veloxion System	**K162979**	March 24, 2017

Predicate devices have 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

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

Comparison of Indications for Use

Device	Indications For Use
Modified Veloxion System (Subject Device)	The Veloxion System is intended for use by trained urologists for endoscopically controlled tissue chip resection and coagulation, and removal of prostate adenomas and bladder tumors (TURBT) via suction channel under continuous flow conditions following resection using a bipolar resectoscope.
Veloxion System K190099 (Primary Predicate) Predicate #1	The Veloxion System is intended for use by trained urologists for endoscopically controlled tissue chip resection and coagulation, and removal of prostate adenomas via suction channel under continuous flow conditions following resection using a bipolar resecting device.

Device	Indications For Use
Predicate #2 K062720 (Predicate system)	S(a)line Resectoscopes are used for endoscopically controlled removal (ablation) of tissue using 0.9% NaCI solution (saline) as the irrigation medium. For Urology: Urological surgical procedures involving the ablation or removal of soft tissue and where associated hemostasis is required. Transurethral resection of the prostate (TURP) and bladder neck. Transurethral resection of the bladder tumors (TURBT) Transurethral incision of the prostate. Coagulation of bleeding in the lower urinary tract. For Gynecology: Tissue cutting, removal, and desiccation as required or encountered in gynecologic hysteroscopic electrosurgical procedures for the treatment of intrauterine myomas, polyps, adhesions, septa, and benign conditions requiring endometrial ablation. Excision of intrauterine myomas. Excision of intrauterine polyps. Lysis of intrauterine septa. Endometrial ablation.
Predicate #3 K042523 (Predicate system)	The Resection Pump 2228 with Resectoscope 8659.xxx is used for endoscopically controlled tissue chip resection and removal of intrauterine polyps, intrauterine myomas or prostate adenomas via suction channel under continuous flow conditions following resection using a high-frequency electrode with a Resectoscope.
Predicate #4 K162979 (Predicate system)	The Veloxion System is intended for endoscopically controlled tissue chip resection and coagulation and removal of prostate adenomas via suction channel under continuous flow conditions following resection using a bipolar resecting device.

VI. Comparison of Technological Characteristics with the Predicate Device

The subject Veloxion System and the previously cleared predicate devices have the same or similar technological characteristics (see Table 1) in terms of basic operating principle and basic design features.

Table 1: Comparison of subject Veloxion System and predicate:

Technological Characteristics	VELOXION SYSTEM (Subject)	VELOXION SYSTEM (Predicate System) K190099 & K162979	Richard Wolf S-Line Resectoscope System (Predicate System) K062720	Richard Wolf Resection Master System (Predicate System) K042523
Energy Type:	Radiofrequency, bipolar	Radiofrequency, bipolar	Radiofrequency, bipolar	Radiofrequency, bipolar
RF Functions:	Cut, Coagulation	Cut, Coagulation	Cut, Coagulation	Cut, Coagulation
Able to Set & Monitor Cavity Pressure?	YES	YES	YES	YES
Irrigation fluid:	Saline	Saline	Saline	Saline
Outer Sheath Working Length:	220mm	**K190099**: 220mm **K162979**: 193mm	186mm	186mm
Outer Sheath OD:	25Fr (8.3mm)	**K190099**: 25Fr (8.3mm) **K162979**: 26Fr (8.6mm)	27Fr (9.0mm)	27Fr (9.0mm)
Inner Sheath OD:	19.5 Fr (6.5mm)	**K190099**: 19.5 Fr (6.5mm) **K162979**: N/A	21 Fr (7mm)	N/A
Max Electrode Extension outside Sheath:	20mm	**K190099**: 20mm **K162979**: 23mm	21mm	21mm
Electrode Wire OD:	0.019”	**K190099**: 0.019” **K162979**: 0.015”	0.010inch to 0.015inch	0.010inch to 0.015inch
Electrode Movement:	Linear Oscillation at 3000cpm	**K190099:** Linear Oscillation at 3000cpm **K162979:** Linear Oscillation at 1000cpm	Stationary on the distal end	Stationary on the distal end

There are minor differences in the technological characteristics between the subject Veloxion System and the predicates. The minor differences do not raise new or different questions of safety and effectiveness for the intended use of the device as it pertains to the expansion of the indications for use.

VII. Performance Data

No new performance testing was required to establish substantially equivalence. Results of tests in reviewed as part of clearance of K190099 and K162979 with comparison testing to the predicates (predicate Veloxion System and Richard Wolf Resectoscope) support substantial equivalence to the identified predicates.

- **Software Verification Testing** was performed using the same protocol reviewed as part of K190099 for all steps affected by the change and documentation updated per FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

VIII. Conclusions

The subject Veloxion System is considered substantially equivalent and as safe and effective as the identified predicate devices (predicate systems).