July 25, 2018

Corinth MedTech, Inc.
Sandeep Saboo
Vice President, Regulatory Affairs
and Quality Assurance
1601 S. De Anza Blvd., Suite 221
Cupertino, CA 95014

Re: K180752
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: June 22, 2018
Received: June 25, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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,

Sharon M. Andrews -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)*

K180752

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 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.

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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K180752: 510(k) Summary

I. Submitter Information

Submitter name:	Corinth MedTech, Inc. 1601 S. De Anza Blvd, Suite 221 Cupertino, CA 95014
Contact person:	Sandeep Saboo Vice President, Regulatory Affairs and Quality Assurance Phone: (408) 996-2517 Fax: (408) 996-0621
Date Prepared:	23 July 2018

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: Richard Wolf Medical Instruments Corporation:
- Resection Pump and Resectoscope for Chip Aspiration (K042523)
- Hystero Pump II 2222 and Fluid Monitoring 2223 (K022449)

Predicate: ERBE, USA Inc., ERBE ESU Model VIO 300D with Accessories (K023886)
Predicate: Veloxion System (cleared per K162979)

None of the predicates have been 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 Resecting Device Kit:
  - Veloxion Resecting Device
  - Sheath
  - Continuous Flow Optical Obturator
- Veloxion Fluid Control Set
- Veloxion Saline Pole

The Veloxion System also includes the following Class I accessories for handling of waste collected from the patient (these items apply no aspiration or irrigation to the patient, they only handle waste after it is already outside the patient), which includes:

- Waste Accessory Bag for collection of waste aspirated form the patient and from under patient's buttocks,
- Waste Accessory Tubing for collection of waste from under the patient's buttocks
- Waste Management Pump for moving the waste to the Waste Bag.

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 a hysteroscope and it monitors the fluid deficit (potential fluid absorbed by the patient's body) to the physician established limit. Therefore:

- 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 and the fluid deficit limits. The software then monitors, controls and notifies the user when the limits are reached or when specific conditions are met.
- The Veloxion Resecting Device is a sterile single use hand held bipolar radiofrequency device configured 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 pressure sensor that provides two independent intrauterine pressure measurement (for redundancy) for monitoring cavity pressure during the procedure thereby facilitating the insufflation function.
- The Veloxion Saline Pole enables monitoring of saline remaining in the saline bag and facilitates the fluid deficit function.

V. Indications for Use

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 the irrigation fluid flowing into and out of the uterus.

There are minor differences in the indications for use for the subject device when compared to the predicate system when the devices that comprise the predicate system are used together per their labeling to perform a hysteroscopy procedure. The predicate system is comprised of the following devices:

- Richard Wolf Resectoscope and Resection Pump for Chip Aspiration
- Richard Wolf Hystero Pump II (Model 2222) and Fluid Monitoring Display (Model 2223)
- ERBE ESU Model VIO 300 D with Accessories

The indications for use for the subject device when compared to the predicate Veloxion System differ with respect to the tissue type.

Comparison of Indications for Use

Device	Indications For Use
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 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.
Richard Wolf Fluid Manager (Predicate K022449) Fluid Monitoring Display (Model 2223) and Hystero Pump II (Model 2222)	The Hysteroscopy Fluid Management System is indicated for liquid distension of the uterus for diagnostic and operative hysteroscopic procedures, and monitoring the volume differential between the irrigation fluid flowing into and out of the uterus.
Resection Pump and Resectoscope for Chip Resection (Primary Predicate, K042523)	The Resection Pump 2228 with Resectoscope 8659.xxx is used for endoscopically controlled tissue chip resection and removal of intrauterine polyps, intrauterine myoma or prostate adenomas via suction channel under continuous flow conditions following resection using a high-frequency electrode with a Resectoscope.
ERBE ESU Model VIO 300 D with Accessories (Predicate, K023886)	The ERBE ESU Model VIO 300 D with Accessories is intended to deliver High Frequency (HF) electrical current for the cutting and/or coagulation of tissue.
Veloxion System K162979 (Predicate Device)	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.

The differences in indication statements do not represent a new intended use.

VI. Comparison of Technological Characteristics with the Predicate Device

The Veloxion System (subject device for hysteroscopy) and the *predicate system* (Richard Wolf Resectoscope and Resection Pump for Chip Aspiration (K042523), ERBE ESU Model VIO 300 D with Accessories (K023886) and Fluid Monitoring Display Model 2223 and Hystero Pump II Model 2222 (K022449)) and the previously cleared Veloxion System (K162979) have the same or similar technological characteristics in terms of basic operating principle and basic design features with one key difference being that Veloxion System includes dual, balanced pump system while the predicate system includes single pump for irrigation only. Both systems include roller peristaltic pumps and are to be used with specifically designed fluid monitoring unit and tube sets.

Technological Characteristics	VELOXION SYSTEM (Subject and Predicate)	PREDICATE SYSTEM Devices ERBE ESU Model VIO 300 D with Accessories [K023886] Richard Wolf Resection Pump [K042523] Richard Wolf Fluid Manager [K022449]
Monopolar or Bipolar	Bipolar	Bipolar or Monopolar
Energy Type:	Radiofrequency, Bipolar	Radiofrequency, Bipolar or Monopolar Resection
Optics:	Compatible with commercially available 30degree Endoscopes.	Compatible with 30degree Richard Wolf Endoscope
Able to Set & Monitor Fluid Deficit?	YES	YES
Able to Set Cavity Pressure on the Device?	YES	YES
Continuous Flow? :	YES	YES
Irrigation fluid:	Saline	Saline
Pump?	Dual Pump (Irrigation, Aspiration)	Single Pump (Irrigation only)
Able to Monitor saline remaining?:	YES	NO
Irrigation Flow Rate:	Programmed irrigation flow rate constant for each mode Steady State = 100ml/min, Cut=380ml/min, Coag=100ml/min for Subject & Predicate ASPIRATE=400ml/min for subject and 750ml/min for predicate.	Max. Irrigation flow rate is Set by the User from 150 to 500ml/min. However, actual flow rate depends on the actual cavity pressure and outflow stopcock opening.
Set Pressure Range:	35 to 125mmHg (subject) 15 to 60mmHg (predicate)	15 to 150mmHg
Positive Action to Increase Above 100mmHg:	YES (subject) 40mmHg (predicate)	YES
Pressure Sensor:	Dual, independent, direct sensing of cavity pressure	Dual, independent, pressure sensing of Irrigation tube (indirect measurement)
Over-pressure condition detection:	YES	YES
Maximum Allowable Actual Cavity Pressure	135mmHg for 5 seconds (subject) 75mmHg (predicate)	200mmHg for 5 seconds
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."**	• Continuous notification tone • Over-pressure display icon is illuminated and Pressure Display flashes
Set Fluid Deficit Range:	From 250 to 2500ml. Device stops when limit is reached (subject only)	From 0 to 2000ml but user can exceed 2500ml, if needed after reaching 2000ml limit.
Fluid Deficit Rate ≥ 300ml/min notification to user?	YES (subject only)	YES
Notification to user with pause when Actual fluid deficit is 1000ml?	YES (subject only)	NO
Notification to user when Actual fluid deficit is 250ml less than Set fluid deficit?	YES (subject only)	NO
Shaft OD (Sheath):	With Sheath Assembled: 26Fr (8.6mm)	With Sheath Assembled: 27Fr (9.0mm)

Technological Characteristics	VELOXION SYSTEM (Subject and Predicate)	PREDICATE SYSTEM Devices ERBE ESU Model VIO 300 D with Accessories [K023886] Richard Wolf Resection Pump [K042523] Richard Wolf Fluid Manager [K022449]
Working Length:	Sheath Working Length: 193mm	Sheath Working Length: 186mm
Materials (Electrode/ Insulation):	Electrode: Tungsten (99.95% purity) Insulation: FEP	Electrode: Tungsten Electrode Insulation: PTFE
How Supplied (Sterility):	Sterile, Single Use (Veloxion Resecting Device Kit)	Sterile component: Electrode Non-Sterile, Reusable Components: Working Element Outer Sheath Obturator

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

- The Veloxion System includes a dual, balanced pump system for a more controlled cavity pressure.
- The Veloxion System includes programmed flow rates that are equivalent to flow rate delivered using the predicate system which also varies based on user adjustment of outflow stopcock.
- The patient contacting components of the Veloxion System are sterile, single use while the predicate system components are sterile, single use for some components and reusable for other components.

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
  - Simulated Use: Tissue resection and spot coagulation, regulation of cavity pressure
  - Durability Testing: Electrode durability testing for tissue resection and coagulation.
  - Fluid deficit testing
  - Comparative testing to predicate for electrode durability, pressure control and fluid control.
  - 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 system*:

- Richard Wolf Resectoscope and Resection Pump for Chip Aspiration,
- ERBE ESU Model VIO 300 D with Accessories, and
- Richard Wolf Fluid Manager (Fluid Monitoring Display (Model 2223) and Hystero Pump II (Model 2222)).

as well as the previously cleared Veloxion System (K162979).