May 14, 2020

FHC, Inc.
% Craig Pagan, Consultant
C2C Development, LLC
1135 W NASA Blvd, Suite 500
Melbourne, Florida 32901

Re: K200169

Trade/Device Name: VFS1 Bipolar Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 10, 2020
Received: April 14, 2020

Dear Craig Pagan:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K200169

Device Name
VFS1 Bipolar Electrosurgical Generator

Indications for Use *(Describe)*

The VFS1 Bipolar Electrosurgical Generator is indicated for use in micro, macro, and endoscopic bipolar irrigation, cutting and coagulating of tissue and the coagulation of blood vessels in all types of surgery.

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.

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SECTION 5 510(K) SUMMARY

1. Submitter's name, address, telephone number, a contact person, and the date the summary was prepared:

FHC, Inc.
1201 Main Street
Bowdoin, ME-04287
Tel: 207-666-5651
Fax: 207-666-8292

Contact: Kelly Moeykens

Preparation Date: April 6th, 2020

2. Name(s) of the Device:

Proprietary/Trade Name:	VFS1 Bipolar Electrosurgical Generator
Common Name:	Bipolar Electrosurgical Generator or Electrosurgical Generator
Regulation Number	21 CFR 878.4400
Regulation Name:	Electrosurgical device
Classification Panel	General and Plastic Surgery
Product Code:	GEI
Regulatory Class:	II

3. Legally Marked Predicate Device to which the submitter claims substantial equivalence:

Trade Name:	Malis Bipolar 2000 Electrosurgical Generator
510(k) #:	K050364
Product Code:	GEI
Decision Date:	March 9th, 2005

Trade Name:	MALIS™ Irrigation Module 1000
510(k) #:	K033499
Product Code:	GEI
Decision Date:	November 28th, 2003

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4. Description of device:

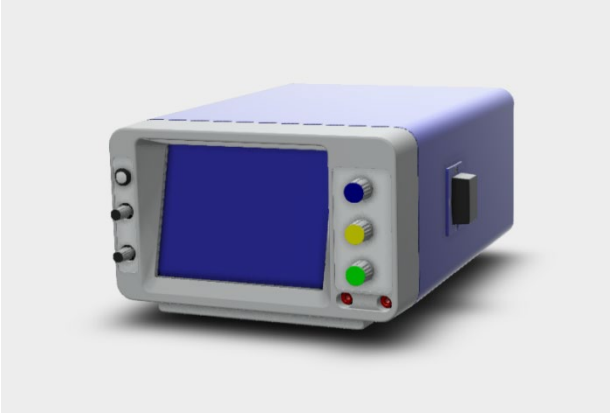
The VFS1 Bipolar Electrosurgical Generator (referred to as generator or VFS1 Generator) is designed to cut and coagulate living human tissue during surgical procedures. The system provides 1 MHz Radio Frequency (RF) energy that is user/operator selectable based on the surgical procedure undertaken. The generator is configured for bipolar output and is earth isolated, to minimize leakage current, thus providing increased patient comfort and safety. The system will be provided with safety features that are continuously monitored and will provide warnings and/ or alerts when critical parameters exceed specified limits.

The VFS1 Generator is designed to cut and coagulate living tissue during surgical procedures. The system includes a bipedal footswitch. The generator is equipped with a tone generator to provide audible feedback each time cutting, or coagulation is performed. The generator incorporates a variable-rate irrigation pump to provide saline flow during procedures.

The VFS1 Generator is compatible with a variety of reusable and disposable bipolar products; i.e., insulated mirror finish bipolar forceps, disposable nonstick bipolar forceps, bipolar instruments as well as disposable bipolar cords and tubing products.

Items that are included in the system are:

- VFS1 generator -CO 840
- Footpedal- CO 841

C0840	Valley Forge Scientific VFS1 Bipolar Electrosurgical Generator	
C0841	Electrosurgical Foot Pedal	

5. Statement of Indications for Use:

The VFS1 Bipolar Electrosurgical Generator is indicated for use in micro, macro, and endoscopic bipolar irrigation, cutting and coagulating of tissue and the coagulation of blood vessels in all types of surgery.

6. Intended Use

The VFS1 Bipolar Generator is intended for use in surgical procedures for cutting tissue and coagulating blood vessels. Procedures must be performed by a surgeon with experience in the use of electrosurgical devices and generators.

7. Comparison of Technological Characteristics to Predicate Devices

Technological Characteristics	**Valley Forge Scientific (division of FHC Inc.) VFS1 Electrosurgical Generator**	**Valley Forge Scientific Corp. Malis 2000 Bipolar Electrosurgical System**	**PREDICATE Malis Irrigation Module 1000**
Modalities	Electrosurgical Cutting and Coagulation Irrigation	Electrosurgical Cutting and Coagulation	Irrigation
Environment of Use	Hospitals and Clinical Settings where electrosurgery is used.	Hospitals and Clinical Settings where electrosurgery is used.	Hospitals and Clinical Settings where electrosurgery is used.
Power Source	AC Voltage from wall receptacle	AC Voltage from wall receptacle	AC Voltage from wall receptacle
Device (System) Components	- Generator - Foot pedal - Power Cord - Cord/Tubing Set - Irrigation Module(check)	- Generator - Foot pedal - Power Cord - Cord/Tubing Set	- Peristaltic Pump - Foot Pedal
Display Screen Details	LCD Display, displays: Cut and Coag Power Settings Power Units Tone Volume and Brightness Settings System Errors and Warnings Irrigation Setting	LCD Display, displays: Cut and Coag Power Settings Power Units Tone and Voice Volume and Brightness Settings System Errors and Warnings Absent	Built in Numeric display

Technological Characteristics	Valley Forge Scientific (division of FHC Inc.) VFS1 Electrosurgical Generator	PREDICATE Valley Forge Scientific Malis 2000 Bipolar Electrosurgical System	PREDICATE Malis Irrigation Module 1000
Pump Head Type	Peristaltic	N/A	Peristaltic
Motor Type	DC electric motor	N/A	DC electric motor
Irrigation Delivery Method	Tubing set with industry standard connectors	N/A	Tubing set with industry standard connectors
Patient interface	Bipolar forceps	N/A	Bipolar forceps
Liquid Source	Saline bag	N/A	Saline bag
Delivery Rate	Slow drip, medium drip, fast drip	N/A	Slow drip, medium drip, fast drip
RF Output Mode	Bipolar	Bipolar	N/A
RF Output Power Range	Cut: 0 to 100 Watts Coag: 0 to 50 Watts	Cut: 0 to 300 Watts Coag: 0 to 50 Watts	N/A
RF Output Waveforms	Cut: 1 MHz sinewave Coag: 1 MHz damped aperiodic	Cut: 1 MHz sinewave Coag: 1 MHz damped aperiodic	N/A
Output Power Controls	Rotary Switches Pushbutton Switches	Rotary Switches	Rotary Switches
Power Activation	Foot pedal	Foot pedal and Finger switches	Foot pedal

8. Performance Data

Non-clinical: Basic mechanical and functional capabilities were tested for the subject electrosurgical generator to determine substantial equivalence to the predicate device. This also includes a Comparibility Study of the subject device and the predicate device. Report Refer to section 18 for details.

The following is a summary of components and testing performed:

- **<u>VCP-09-103 – VFS1 Hardware Verification Testing</u>**
  Testing and inspection performed on the VFS1 Electrosurgical Generator, to verify compliance with the Product Development Specification, DSl-09-100. Testing included:
  - Input Voltage
  - Input Frequency
  - Input Protection

- Output Waveform
- RF Power Output
- RF Output vs Load Resistance
- RF Overcurrent Protection
- Over-dosage Protection
- Irrigation
- Real Time Clock
- Mechanical
- Operating Conditions
- Storage Conditions
- Cooling
- Transportation
- Shock
- Cleaning
- Front Panel Connections
- Rear Panel Connections
- Power Cord
- Front Panel Controls
- Rear Panel Controls
- Display

All testing met specifications.

- **VCP-09-109 – VFS1 Comparibility Study Report**
  Testing was performed on the VFS1 Electrosurgical Generator to verify proper operation of the generator with all the components and accessories working together as a system. Testing included Ex Vivo testing for Cut and Coag using steak, liver and kidney tissue samples. All testing was found to be acceptable.

- **ROH-09-100 – VFS1 ROHS Verification Report**
  RoHS Compliance was verified for all components and subassemblies of the VFS1 Surgical Generator, Model CO840.

- **VDP-09-100 – Shipping Test Report**
  Testing was performed to confirm that the external packaging configuration for the VFS1 Electrosurgical Generator provides a high probability of safe and intact arrival at the destination by confirming that the integrity of the packaging and its components withstand simulated shipping and handling stress and by demonstrating that the shipping and handling stresses have no adverse effect on the VFS1 Generator performance. Testing was performed per ISTA-3A Shipping Test and met all requirements.

Clinical: No clinical data was used to determine substantial equivalence.

9. Conclusion

Based on the non-clinical performance data performed comparing the VFS1 Electrosurgical Generator to the predicate devices (Malis 2000 Bipolar Electrosurgical System and the Malis Irrigation Module 1000), it is concluded that the device is as safe, as effective, and performs as well as or better than the predicate device.