March 20, 2023

F Care Systems USA LLC
% Shilpa Gampa
Delivery Manager and US Agent-MDV
Freyr, Inc.
150 College Rd W, #102
Princeton, New Jersey 08540

Re: K220725
Trade/Device Name: HPR45i
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 18, 2023
Received: January 20, 2023

Dear Shilpa Gampa:

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.03.20 12:13:51 -04'00'

Mark Trumbore, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220725

Device Name
HPR45i

Indications for Use *(Describe)*
HPR45i electrosurgical electrode is intended to conduct radio frequency (RF) current for coagulation from the RF electrosurgical generator to target soft issue in a broad range of surgical procedures. The device is a prescription use (Rx) device.

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.

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510(K) Summary

This 510(K) summary of safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: March 14, 2023

1. Submitter Information:

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Date Prepared:	03-March-2022

2. Device Identification:

Device Trade Name:	HPR45i
Common Name:	Electrosurgical electrode
Classification Name:	Electrosurgical cutting and coagulation device and accessories

Table 1 Device Identification

Regulation Number	Product Code	Device Class
878.4400	GEI	Class II

3. Legally Marketed Equivalent Device:

Table 2 Predicate Device

510(k) Number	Device Name	Manufacturer
K081791	E-Z Clean Electrosurgical Electrode	Megadyne Medical Products, Inc

4. Device Description

HPR45i is a monopolar electrosurgical electrode intended to remove tissue and control bleeding using radio frequency electrical current. It is a prescription use device which is intended to be used by a licensed doctors or specialist in the healthcare facility/ hospital.

The HPR45i is supplied sterile (Sterilized by EO Sterilization) and is not intended to be reused. It consists of 3 different parts such as HPR45i handle, output cable and stainless-steel tube. The stainless-steel tube is insulated over most of its exposed length, and it is connected to the stainless steel (AISI316L) tip at the end. The material of insulation is PTFE. The stainless steel (AISI316L) tip and PTFE insulation are the direct patient contacting parts of the device. It is an external communicating device with limited duration (<24hrs) of contact with tissue and blood.

The HPR45i is designed to be used in combination with a radiofrequency generator (MedRF4000 (K210077) manufactured by F Care Systems USA LLC) for the application of haemostasis of soft tissue. The RF signal, which is generated by the generator, passes through the HPR45i, and is applied on the soft tissue by means of the HPR45i tip. When contact is made with tissue, the RF signal is converted into heat resulting in the bleeding to stop and haemostasis to appear. The HPR45i has no power regulating function, and it does not contain a diagnostic or monitoring function.

Compatible device:

- MEDRF 4000

No accessories are required to achieve the intended purpose of the HPR45i.

5. Intended Use/Indications for Use

HPR45i electrosurgical electrode is intended to conduct radio frequency (RF) current for coagulation from the RF electrosurgical generator to target soft tissue in a broad range of surgical procedures. The device is a prescription use (Rx) device.

6. Substantial Equivalence Comparison

The substantial equivalence comparison table is provided in Table 3.

Table 3 Comparison of Technological Characteristics between subject and predicate device

Characteristic / Feature	E-Z CLEAN Electrosurgical Electrode (Predicate Device)	HPR45i (Subject device)	Comments
Device Name	E-Z CLEAN Electrosurgical Electrode	HPR45i Electrode	N/A
Manufacturer Name	Megadyne Medical Products, Inc.	F Care Systems	N/A
510(K) Number	K081791	K220725	N/A
Classification Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	Same
Product code	GEI	GEI	Same
Regulation Number	21 CFR 878.4400	21 CFR 878.4400	Same
Panel	General & Plastic Surgery	General & Plastic Surgery	Same
Class	Class II	Class II	Same
Indications for Use	E-Z Clean electrosurgical electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the RF electrosurgical generator to target soft tissue in a broad range of surgical procedures requiring the use of electro surgery for cutting and cauterization. Some tip configurations have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the generator's Advanced Cutting Effect (ACE) mode.	HPR45i electrosurgical electrode is intended to conduct radio frequency (RF) current for coagulation from the RF electrosurgical generator to target soft tissue in a broad range of surgical procedures. The device is a prescription use (Rx) device.	Similar. Refer Justification 1
Mode of Action	Thermocoagulation (RF) of tissue by administration of high frequency energy	Thermocoagulation (RF) of tissue by administration of high frequency energy	Same

Characteristic / Feature		**E-Z CLEAN Electrosurgical Electrode (Predicate Device)**	**HPR45i (Subject device)**	**Comments**
Components		Electrosurgical Generator, active electrode, return electrode, foot pedal.	Electrosurgical Generator was approved along with the neutral electrode, active electrode, foot pedal,	Same
Output Energy type		Radio Frequency	Radio Frequency	Same
Mode of delivery		Disposable Electrode	Disposable Electrode	Same
Modality		Monopolar	Monopolar	Same
Rx or OTC		Prescription Use	Prescription Use	Same
Maximum power		300 watts	25 Watts	Different. Refer justification 2.
Maximum Voltage		≤10.8 KV	800 v	Different. Refer justification 3.
Maximum Frequency		510 kHz	4MHZ	Different. Refer justification 4.
Tip Head Dimensions	Tip length of Blade Electrode	21 mm	N/A	This configuration is not available in subject device.
	Tip length of Ball Electrode	5.3 mm	N/A	This configuration is not available in subject device.
	Tip length of Needle Electrode	4.2 mm	10 mm	Different. Refer justification 5.
Tissue/ Tip head surface-contacting area	Blade electrode	53mm²	44m²	Similar
	Ball electrode	56mm²		
	Needle electrode	5.8mm²		
Electrode Material		300 series stainless steel	Stainless steel, AISI316L	Same
Patient Contacting Material		SS, Polyolefin, PTFE, vinyl, and Silicone	AISI316L Stainless steel and PTFE	Same
Insulation Material		Polyolefin and PTFE	PTFE	Similar. Refer Justification 6.

Characteristic / Feature	E-Z CLEAN Electrosurgical Electrode (Predicate Device)	HPR45i (Subject device)	Comments
Sterilization	Radiation Gamma EO	EO	Same
Single use	Yes	Yes	Same
Coating Material	PTFE	PTFE	Same

Justification 1: The minor difference in the intended use of the device is that HPR45i is intended only for coagulation not for cutting but the predicate device is intended to be used for both cutting and coagulation. However, this difference will not raise any concern on the safety and effectiveness of the subject device since coagulation is covered under the intended use of predicate device.

Justification 2: The predicate device, E-Z CLEAN Electrosurgical Electrode is used for both cutting and coagulation whereas HPR45i is not used for cutting, only control of hemostasis, therefore the maximum power of HPR45i (25 W) is much lower than the predicate (300 W).

Justification 3: The predicate device, E-Z CLEAN Electrosurgical Electrode is used for both cutting and coagulation whereas HPR45i is not used for cutting, only control of hemostasis, therefore the maximum voltage of HPR45i (800V) is much lower than the predicate (≤10.8 KV).

Justification 4: The predicate device, E-Z Clean Electrosurgical uses a lower frequency (510 kHz), the HPR45i uses a higher frequency (4MHZ). The higher frequency in HPR45i has no effect on efficiency as evidenced by the tissue testing.

Justification 5: The tip length of HPR45i and E-Z Clean Electrosurgical Electrode different. However, tip length of HPR45i (10mm) tip length falls within the tip length (21mm, 5.3mm and 4.2mm) of the different versions of the predicate device, E-Z Clean Electrosurgical Electrode.

Justification 6: The PTFE material was selected as it was more durable material than polyolefin. Therefore, the above difference does not raise any safety or effectives tissue for the subject device

7. Summary of Non- Clinical Data

The non-clinical performance tests have been executed in line with recommendations of the FDA guidance: "Premarket Notification [510(k)] Submissions for Electrosurgical Devices for General Surgery" – Guidance for Industry and Food and Drug Administration Staff, August 15, 2016. The following performance tests were carried out for HPR45i:

Table 4 Non-Clinical Performance Tests

S. No	Test Performed	Results
1	ESU Testing	Pass
2	Active Components/ Accessories Testing	Pass
3	Neutral Electrode Testing	Pass
4	Miscellaneous Components/ Accessories Testing	Pass
5	Capacitive Coupling Testing	Pass
6	Electrical safety and Electromagnetic Compatibility	Pass
7	Thermal Effect on Tissue	Pass

HPR45i comply with the following international and FDA-recognized consensus standards:

- IEC 60601-2-2: 2018 Medical electrical equipment - Part 2-2: Requirements for the safety of high frequency surgical equipment.
- IEC 60601-1:2006/A11:2011/A1:2013 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 Edition 4.0 2014-02 - Medical Electrical Equipment- Part 1-2: General Requirements for Basic safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests.
- ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- 10993-3 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
- 10993-4 Third edition 2017-04 - Biological Evaluation of Medical Devices - Part 4: Selection of Tests for interactions with Blood.
- ISO 10993-5: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11: Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
- ISO 10993-18 Second edition 2020-01 - Biological Evaluation of Medical Devices - Part 18: Chemical characterization of medical device materials within a risk management process.

HPR45i Monopolar Electrodes are sterilized by using a validated ethylene oxide cycle. The sterilization cycle has been validated to ensure a sterility level of (SAL) 10-6 in accordance with ISO 11135. Furthermore, the packaging integrity and accelerated aging test were performed on the subject device to support the proposed shelf life.

All non-clinical tests met the acceptance criteria specified in the standards.

8. Summary of Clinical Data

As per FDA's guidance document, **"Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery"** Clinical data are generally not necessary to support 510(k) submissions for electrosurgical devices that are intended for general surgery indications. Moreover, indications for use of HPR45i or device technology or mechanism of action is not significantly different when compared to the predicate device. Therefore, no clinical data was submitted for HPR45i.

9. Conclusion

Based on the comparison and analysis above, the proposed device "HPR45i" is determined to be Substantially Equivalent (SE) to the predicate device "E-Z Clean Electrosurgical Electrode".