June 30, 2023

Compal Electronics, Inc
Casper Chen
Senior Director
No. 581, Ruiguang Rd., Neihu District
Taipei City, 11492
Taiwan

Re: K223135
Trade/Device Name: AblatePal Radiofrequency Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 29, 2023
Received: June 1, 2023

Dear Casper Chen:

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: 2023.06.30 15:38:18 -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)*
K223135

Device Name
AblatePal Radiofrequency Ablation System

Indications for Use *(Describe)*
The AblatePal Radiofrequency Ablation System is designed to provide monopolar radiofrequency (RF) energy to be used for coagulation and ablation of soft tissue.

The device is a prescription 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.

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510(k) Summary

1. Date of Summary Preparation

June 28, 2023

2. 510(k) Submitter/Holder

Compal Electronics, Inc.
No. 581, Ruiguang Rd.,
Neihu Dist. Taipei, 11492, Taiwan (R.O.C.)

3. Contact: Casper Chen

Senior Director of Medical Product Division

Email: Casper_Chen@compal.com

Address: No. 581, Ruiguang Rd.,
Neihu Dist. Taipei, 11492, Taiwan (R.O.C.)

4. Device

Device Trade Name:	AblatePal Radiofrequency Ablation System
Device Common Name:	RF Ablation System
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Regulation:	21 CFR 878.4400
Regulatory Class:	II
Product Code:	GEI

5. Predicate Device

The AblatePal Radiofrequency Ablation System is substantially equivalent to the following, commercially available predicate devices:

Device Name	Classification Name and Class	510(k) Number(s)
Cool-tip™ RF Ablation System	Electrosurgical, Cutting & Coagulation & Accessories	K042216 (Primary Predicate Device)

6 Intended Use / Indications for Use

The AblatePal Radiofrequency Ablation System is designed to provide monopolar radiofrequency (RF) energy to be used for coagulation and ablation of soft tissue.

The device is a prescription device.

7. Device Description

The AblatePal Radiofrequency Ablation System (subject device) (HFM01-MD2202) is a monopolar radiofrequency (RF) generator with dedicated components and accessories. The generator can be operated in only impedance mode that use various combinations of time, tissue temperature, tissue impedance, and manual control. An interactive touchscreen display allows user input to the generator and displays informational signals and alert messages. Active electrodes are placed in the tissue to deliver RF energy to the tissue to be ablated. Only one electrode can be attached to the generator and can be used individually. During the ablation of tissue, RF current flows from the generator to an active electrode which delivers the current to the patient. The RF current flows from the active electrode through the patient's body tissue to the Neutral Electrode, which recovers the current and returns it to the generator. The resistance to the current, provided by the patient's tissue, produces the heat that is necessary for ablation of tissue.

The dedicated system components include:

- RF Generator, radiofrequency generator
- Ablation Foot Switch (HFM01-AF0002): Single Foot Switch. Pressing the foot switch that RF Generator starts or stops ablating.
- Power Control Foot Switch (HFM01-AF0001): Double Foot Switch. Pressing the foot switch to adjust power in whole units of Watts that the RF Generator will deliver during the ablation. The blue foot switch can increase the power, and the yellow foot switch can decrease the power.
- Power Cord (WS-001H+WS-002): A line cord that provides AC power to the RFA system.
- Electrode Kit (HFM01-AC0001~ HFM01-AC0006), including radiofrequency electrode, inflow-outflow tubing sets and Neutral Electrodes (HFM01-AE0001).

The generator is packaged individually and is always supplied with the accessory items: footswitch and cables. The electrode kit HFM01-AC0001~ HFM01-AC0006 is separately packaged.

The following AblatePal Radiofrequency Ablation System compatible accessories are single use:

- Electrode Kit (HFM01-AC0001~ HFM01-AC0006), including a radiofrequency electrode, inflow-outflow tubing sets and Neutral Electrodes.

8. Comparison of Technological Characteristics with the Predicate Device

The AblatePal Radiofrequency Ablation System (subject device) relies on the same principles of operation and has similar performance characteristics, with respect to its intended use, as the predicate devices. The AblatePal Radiofrequency Ablation System combines the functional characteristics of the predicate Cool-tip™ generator (K042216).

There are three main differences between the AblatePal Radiofrequency Ablation System and the predicate Cool-tip™ RF Ablation System

1. New larger patient Neutral Electrode compared to the predicate device.

2. The generator combines the functional characteristics of the predicate Cool- tip™ generator into a single RF generator that includes a different user interface and software controls.

3. The addition of several optional accessories, specifically, footswitches.

Unlike the predicate device, the AblatePal Radiofrequency Ablation System has only one category of RF Ablation electrodes (monopolar). The AblatePal Radiofrequency Ablation System active electrodes deliver RF energy from the AblatePal Radiofrequency Ablation System generator for the ablation of tissue when used with an irrigation pump, which must comply with IEC 60601-1, and electrode kits. An electrode kit with a single active electrode (sterile), inflow-outflow tubing sets (sterile) and two Neutral Electrodes (non-sterile) are available. All kit items are single use.

Description	**Subject Device** AblatePal Radiofrequency Ablation System (K223135)	**Predicate Device** Cool-tip™ RF Ablation System (K042216)	**Comparison**
Indications for Use	The AblatePal Radiofrequency Ablation System is designed to provide monopolar radiofrequency (RF) energy to be used for coagulation and ablation of soft tissue. The device is a prescription device.	The Valleylab Cool-tip RF System (generator and accessories) is intended for the use in percutaneous, laparoscopic, and intraoperative coagulation and ablation of tissue, such as partial or complete ablation of non-resectable liver lesions.	The indication of "percutaneous, laparoscopic, and intraoperative coagulation and ablation of tissue, such as partial or complete ablation of non-resectable liver lesions" has been removed from the subject device.
Prescription or OTC	Prescription	Prescription	Same
ESU • Major function	Monopolar impedance monitor: Range:25-1000 Ohm Resolution:1 Ohm Accuracy:50-200 Ohm (± 10%) continuity monitor: temperature Range: 10-99°C Resolution: 0.1°C Accuracy: ±4°C	Monopolar impedance monitor: Range:0-1000 Ohm Resolution:1 Ohm Accuracy:50-100 Ohm (± 10%), 500-1000 Ohm (± 20%) continuity monitor: temperature Range: 10-99°C Resolution: 1°C Accuracy: ±4°C	Same: Monopolar Impedance monitoring of the subject device is in the range of that of the predicate device Same: continuity monitor
ESU • Performance specifications	Output frequency: 480kHz±10% Waveform: AC sin wave (110 V)	Output frequency: 480kHz±10%	Accuracy of the subject device is in the range of that of the

	Power output: 0-200W Max 50 Ohm output load. Accuracy is ±20%. Voltage output: 100Vrms at 50Ω in 200W	Waveform: AC sin wave (100/120 V) Power output: 0-200W Max 50 Ohm output load. Accuracy is ±15%. Voltage output: 100Vrms at 50Ω in 200W	predicate device Others are same
ESU • Physical specifications	12.0 kg 39 x 32.5 x 22.5 cm	8.0 kg 41.8 x 28.0 x 14.0 cm	ESU of the subjective device is heavier than that of the predicate device
Active accessory • Monopolar or bipolar • Physical dimensions and design (e.g., size, length, connector type) • Rated voltage • Materials (electrode, insulation, coating, etc.)	- Monopolar - Length: 10/15/20cm - Exposure: 0.5/1/2/3 cm - Diameter: 17/18 G - EO sterilization - Specification: 100V Vrms,2A	- Monopolar - Length: 10/14.4/15/20/25 cm - Exposure: 0.7/1/2/3/ cm - Diameter: 17G - EO sterilization - Specification: 100V Vrms,2A	Length, exposure, diameter of the subject device is in the range of that of the predicate device Others are same
Neutral electrodes • Conductive or capacitive • Physical specifications • Materials	-Conductive -Material: Al alloy - Specification: 23x14 cm	-Conductive -Material: Al alloy - Specification: 22x13 cm	Neutral electrodes of the subjective device are larger than those of the predicate device
Miscellaneous accessories • Functions • Performance specifications • Physical specifications • Materials	Ablation Foot Switch (Single Foot Switch): Pressing the foot switch that RF Generator starts or stops ablating. Power Control Foot Switch (Double Foot Switch): Pressing the foot switch to adjust power in whole units of Watts that the RF Generator will deliver during the ablation. The blue foot switch can increase the power, and the yellow foot switch can decrease the power. - Specification: 25VAC,5A - Materials: Plastic	N/A	Addition of Ablation Foot Switch and Power Control Foot Switch. Performance data is provided in HFM01-F-24 System test report (section 20-22) and IEC 60601-2-2 report to support that, even with significant differences, the device is as safe and effective as the predicate.

9. Performance Testing

Non-clinical performance testing was performed, and reports are provided in support of substantial equivalence with the predicate device.

9.1 Summary of Bench Testing

Electrical Safety and Electromagnetic Compatibility (EMC):

Bench testing and verification were conducted to ensure proper device function. At the system level, electrical safety and electromagnetic compatibility were evaluated to establish conformity to the applicable IEC 60601 safety standards, as identified below.

- IEC 60601-1:2005/AMD1:2020 Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2021 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
- IEC 60601-2-2:2017 Medical Electrical Equipment Part 2-2: Particular Requirements for the Basic Safety and Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories

The performance and safety of the AblatePal Radiofrequency Ablation System was characterized using laboratory (bench) verification and simulated-use validation testing consisting of soft tissue performance providing a characterization of the AblatePal Radiofrequency Ablation System ablation performance across the complete range of modes, electrodes, and in three tissue types: liver, kidney, and muscle. Ablation performance verifying the equivalence between the predicate Cool-tip™ RFA System and AblatePal Radiofrequency Ablation System when used with the AblatePal Radiofrequency Ablation System was performed at the system and sub-system level to demonstrate the following:

- AblatePal Radiofrequency Ablation System RF Ablation Generator meets all design and performance requirements necessary to prove substantial equivalence with the predicate device,
- AblatePal Radiofrequency Ablation System RF Ablation Generator meets all ablation performance design requirements and to demonstrate the ablations zone dimensions created with the AblatePal Radiofrequency Ablation System Ablation Generator (subject) and Cool-tip™ RF Ablation Generator (predicate) are equivalent,
- The AblatePal Radiofrequency Ablation System Neutral Electrode, and RF Ablation cable meet design and performance requirements,
- The AblatePal Radiofrequency Ablation System with Ablation Generator meets IEC, EMC, regulatory and safety requirements,
- Validate the usability of AblatePal Radiofrequency Ablation System Ablation Generator (HFM01-MD2202) with the intended users,
- The packaging of AblatePal Radiofrequency Ablation System, including RF Ablation Generator, Neutral Electrode, RF Ablation Electrode Kits, can provide protection during simulated transportation.

9.2 Animal Testing

Ex-vivo testing conducted demonstrated the histological, thermal and ablative performance , as well as procedural safety of the subject device is equivalent to the predicate for the AblatePal Radiofrequency Ablation System intended use.

10. Software

Software for the AblatePal Radiofrequency Ablation System was developed in accordance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, for devices with a Moderate Level of Concern. System level software testing was completed successfully.

11. Biocompatibility

The direct patient contacting devices of the AblatePal Radiofrequency Ablation System are the Neutral Electrode and active electrode. These devices are disposable and intended for single use. These devices were assessed for biocompatibility and potential adverse health effects associated with patient contacting disposable devices and were determined to be acceptable.

Direct Patient Contacting Devices:

Neutral Electrode:

The Neutral Electrode is used to collect the RF energy delivered at the active electrode and return it to thegenerator.

The patient contacting materials in the Neutral Electrode were tested to thebiocompatibility requirements shown below.

- Cytotoxicity
- Sensitization
- Skin Irritation

Active Electrode:

Active electrodes are placed in the tissue to deliver RF energy to the tissue being ablated.

The patient contacting materials in the Active Electrode were tested to the biocompatibility requirements shown below:

- Cytotoxicity
- Sensitization
- Intracutaneous reactivity
- Acute Systemic Toxicity
- Pyrogen

12. Sterilization and Shelf life

The active electrodes are provided sterile with EtO with SAL of 10^{-6}, are intended for use within the sterile field, and are designed for single use only.

Electrode kit:
The AblatePal Radiofrequency Ablation System electrode kits, including active electrode and tubing sets, are sterilized with EtO to a sterility level of 10^{-6}. The sterile packaging is labeled as sterile for 3 years immediately following the date of manufacturing.

The single use neutral electrode are not provided sterile and have a shelf life of 1.5 years.

13. Conclusion

The AblatePal Radiofrequency Ablation System (subject device) and Cool-tip™ RF Ablation System (predicate device) have equivalent power and ablation performance characteristics based on verification and validation testing, and pre-clinical studies. Verification testing of the optional accessories consisting of the footswitch was conducted for their use with the subject device. As a result, the AblatePal Radiofrequency Ablation System has been shown to be substantially equivalent to the predicate device and does not raise different questions of safety and effectiveness.