March 2, 2023

Plasma Concepts
% Richelle Helman
Senior Regulatory Consultant
MEDIcept, LLC
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K223440
Trade/Device Name: Plasma Pen (Plasma MD); Plasma Pen (Plasma +)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: QVJ
Dated: February 6, 2023
Received: February 6, 2023

Dear Richelle Helman:

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: 2023.03.02 13:29:42 -05'00'

On behalf of
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223440

Device Name
Plasma Pen (Plasma MD);
Plasma Pen (Plasma +)

Indications for Use *(Describe)*
The Plasma MD or Plasma + is intended for the removal and destruction of skin lesions and coagulation of tissue.

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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Date: 22-February-2023

Company: Plasma Concepts
800 W Cummings Park
Woburn, MA 01801
Phone: (617) 519-5570

Official Contact: Richelle Helman
Senior Regulatory Consultant

Proprietary or Trade Name: Plasma MD and Plasma +

Common/Usual Name: Electrosurgical cutting and coagulation device and accessories

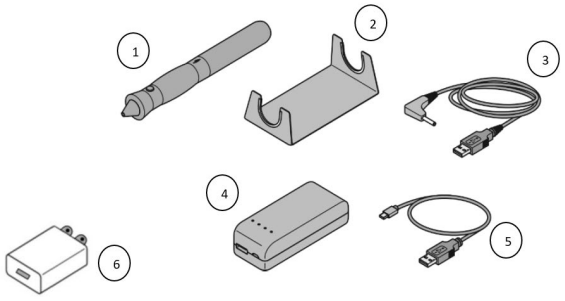
Classification Name: Electrosurgical, Cutting & Coagulation & Accessories

Regulation Number: 21 CFR 878.4400, Class II
Classification Product Code: GEI

Predicate Device: K201738: SubNovii Advanced Plasma Technology

Device Description:
The Plasma Pen utilizes a treatment method called plasma sublimation, which causes controlled skin damage through the generation of an electrical arc. The arc between the disposable tip and the skin is created by a radio frequency generator housed in an electrosurgical unit (handpiece) that ionizes the gas particles in the air. A straight disposable tip is available with the system. The handheld device is cordless and is charged in a docking/charging station prior to use.

The system components include the following:
1. Plasma Pen (Plasma MD (with 2 level switch) and Plasma+ (without switch)
2. Docking station for Plasma Pen
3. Cable for Plasma Pen
4. Power bank battery
5. Cable for power bank battery
6. Charging Block



Indications for Use:
The Plasma MD or Plasma + is intended for the removal and destruction of skin lesions and coagulation of tissue.

Substantial Equivalence:
The Plasma Concepts Plasma Pen is substantially equivalent to the predicate device, the SubNovii Advanced Plasma Technology (510(k) K201738). The table below presents the similarities and differences between the products for substantial equivalence purposes. The differences between the subject device and the predicate device do not raise any new issues of safety and effectiveness. Performance data are available to support substantial equivalence.

Characteristic	**Subject Device:** Plasma Pen	**Predicate Device:** SubNovii Advanced Plasma Technology [510(k) K201738]	**Substantial Equivalence**
Indications for Use	Intended for the removal and destruction of skin lesions and coagulation of tissue.	Intended for the removal and destruction of skin lesions and coagulation of tissue.	**SAME**
Prescription or OTC	Prescription	Prescription	**SAME**
Mode of Operation	Plasma Radiofrequency energy ionizes the air creating a plasma stream	Plasma Radiofrequency energy ionizes the air creating a plasma stream	**SAME**
Output	Monopolar	Monopolar	**SAME**
Power Supply	110-250 VAC 50/60 Hz	110-250 VAC 50/60 Hz	**SAME**
Frequency	40 kHz	40 kHz	**SAME**
Max Power Output	2W	5W	**DIFFERENT** The subject device has a lower max power output, with intended effect still achievable. Refer to table SE.2 below for additional details.
System Components	System consists of a handpiece that incorporates the electrosurgical generator unit, docking station, and an active electrode.	System consists of a handpiece that incorporates the electrosurgical generator unit, docking station, and an active electrode.	**SAME**
Electrical Safety Standards	Complies with IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-2	Complies with IEC 60601-1, IEC 60601-1-2	**SIMILAR** The subject device also complies with IEC 60601-2-2

Characteristic	**Subject Device:** Plasma Pen	**Predicate Device:** SubNovii Advanced Plasma Technology [510(k) K201738]	**Substantial Equivalence**
Thermal Effects on 4 porcine tissues (liver, kidney, muscle and skin) per FDA Guidance Premarket Notification (510(K)) Submission for Electrosurgical Devices for General Surgery	Damage depth of <0.25mm	Damage depth of <0.25mm	**SAME**

From the comparison form above, the subject device and predicate device have similar intended use, are both prescription use, and have the same operating principle and method of removing and destroying skin lesions and coagulating tissue. The differences in the devices do not raise different questions of safety or effectiveness.

Non-clinical performance testing:

Electrical Safety:
Electrical safety and electromagnetic compatibility testing were conducted in accordance with IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-2 to demonstrate the basic safety, essential performance and emissions and immunity characteristics of the device. The testing demonstrated the appropriate electrical safety and electromagnetic compatibility profile for the device.

Bench / Performance Testing –
Comparative performance testing included:

- Electrical system performance
- Output waveform at the rated load
- Testing for thermal effects on tissue in accordance with FDA Guidance “Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery”

The results demonstrated that the device performance was met and was substantially equivalent to the predicate device.

Substantial Equivalence Conclusion
The Plasma Concepts Plasma MD and Plasma + devices have the same technology, principle of operation and indications for use as the predicate device. The performance testing demonstrated that the subject device can perform the same intended use as safely and effectively as the predicate device. Therefore, the subject device is substantially equivalent to the predicate device.