April 6, 2022

Brera Medical Inc.
Paul Dunleavy
President
19 Kramas Lane
Northwood, New Hampshire 03261

Re: K202106
Trade/Device Name: Plasmage System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 16, 2021
Received: August 23, 2021

Dear Paul Dunleavy:

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)*
K202106

Device Name
Plasmage System

Indications for Use *(Describe)*
Removal and destruction of skin lesions and the coagulation of skin 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.

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Traditional 510(k) Summary – Plasmage system
as required by 21 CFR 807.92

A) Sponsor: Brera Medical Inc.

Official Contact: Paul Dunleavy
President
Brera Medical Inc.
19 Kramas Lane, Northwood NH 03261
Phone 888 5801233 ext 101

B) Device Name: Plasmage System
Common Name: Electrosurgical Cutting and Coagulation Device and Accessories
Device Class: Class II
Regulation: 878.4400
Product Code: GEI
Classification panel: General & Plastic Surgery
Submission Type: Traditional 510(k) (Original Submission)

C) Predicate: Bovie Derm 941/942, K161134
Bovie Medical Corporation, Clearwater FL

D) Date Prepared: September 17, 2021

E) Device Description:

The Plasmage system is a radiofrequency based professional device exciting an electrical plasma discharge between a metal tip and the patient skin. The discharge deposit thermal energy in the skin and results in removal and destruction of skin lesions and the coagulation of skin tissue.
The device is operating in monopolar mode only.
The device consists of a console with touch LCD screen and graphic user interface, handpiece with integrated cable, single use electrodes, and foot pedal. The main technical parameters are shown in a comparison table in section G.

F) Intended Use/Indications For Use:

Removal and destruction of skin lesions and the coagulation of skin tissue.

G) Technology Comparison and Substantial Equivalence Discussions

The product code for the subject device is GEI (Electrosurgical Cutting and Coagulation Device and Accessories), regulation number 21 CFR 878.4400,
The predicate device is Bovie Derm 941/942 (K103654), product code GEI, regulation number 21 CFR 878.4400.

The K103654 clearance covers two devices – Derm 941 (capable of only monopolar mode) and Derm 942 (capable of operating in monopolar and bipolar mode). Both devices have identical performance when operated in monopolar mode. Subject device is only capable of monopolar mode.

The following table contains comparison of technological characteristics of subject and predicate devices

	Brera USA K202106	**Bovie Derm 941/942 K161134**	
Predicate	**Subject**	**Primary**	
Product code	**GEI**	**GEI**	
Indications for Use	Removal and destruction of skin lesions and the coagulation of skin tissue	The intended use for the DERM 941 and DERM 942 is for removal and destruction of skin lesions and the coagulation of tissue	
OTC	No	No	
Specifications			
	Plasmage	**Derm 941/942**	**Comparison**
Applicator/electrode	Metal tip	Metal tip	Different shape and size
Electrode material	Stainless steel 316L	Stainless steel 316L	Same
Energy source	Radiofrequency	Radiofrequency	Same
RF Application	Monopolar	941 is monopolar only, 942 is monopolar and bipolar	Same for monopolar mode
RF frequency	100 kHz	368 kHz bipolar, 410 kHz monopolar	SE
RF voltage	Up to 3000 peak to peak	Up to 6300 peak Monopolar	SE
RF power	Up to 5.5 W	Up to 40 W	Different
Energy applied to tissue	Plasma discharge	Plasma discharge	Same
Tissue type	Skin	Multiple tissues types including skin	Same
Treatment duration	Selected by operator	Selected by operator	Same
Weight	1.5 kg	2.3 kg	SE
Size	27 x 25 x 9 cm	22.8 x 18.8 x 10.5 cm	SE
Electrical safety, EMC requirements	Yes	Yes	Same

Discussions

Similarities

The Plasmage suggested indications for use are a subset of the predicate device indication for use. Both Plasmage and predicate device create a small size area of thermal damage used to coagulate or evaporate tissue. Such thermal damage could be used in surgery for hemostasis or to facilitate skin remodeling. Both treatment tips should be manually held at a small distance from the tissue (less than 1 mm) during treatment, while treatment energy is enables by operator using a foot pedal.

The exposure level in both devices is controlled by an operator by selecting power and then controlling exposure duration by visually observing tissue effect and/or training the operator to maintain the combination of power and tip movement speed appropriate for selected clinical

procedure. Subject and predicate devices are using RF energy, such as plasma discharge initiated by radiofrequency waves, at 100 kHz sinusoidal voltage in the subject device and short pulses with central frequency of 410 kHz for monopolar mode of operation in the predicate device. The action of both devices on tissue is predominantly thermal and related to absorption of the energy provided and heating the tissue in the area of energy application. The provided histologies with viability staining show similar size and shape of thermal damage profile created by these devices.
See more information about specific evaluation of the thermal damage profile for Plasmage and comparison with the predicate device in the Discussion of Substantial Equivalence section of the submission.
Like the predicate devices, the Plasmage meets appropriate electrical safety and EMC testing requirements per FDA recognized consensus standards.

Differences
The subject has different output power, RF frequency and applicators. However, these differences do not raise additional safety or effectiveness concerns. Performance tests as listed in the following section H and I demonstrated the subject device has equivalent performance as the predicate device for the proposed indications for use.

Conclusion
The Plasmage and the predicate device have same indication for use, Technology, mechanism of actions, operational principles and performance for the proposed indications for use. The differences between the Plasmage and the predicate devices do not raise additional safety or effectiveness concerns.

H) Performance Testing – bench.
As recommended by the FDA guidance "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery", revised in 2020, a histology study has been performed to evaluate shape and size of thermal damage profile at 3 power settings - minimum, recommended for intended use and maximum power, on *ex vivo* porcine skin. The tissue damage was evaluated with Nitro Blue Tetra Chlorine (NBTC) histological evaluation.

The study demonstrated that treatment by predicate and subject devices produces similar histological and thermal effect on skin tissue, supporting substantial equivalence of the devices.

I) Consensus Standards
The Plasmage System complies with the following FDA recognized consensus standards:

- AAMI ANSI ES 60601-1:2005(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment—Part 1: General requirements for basic safety and essential performance (FDA recognition #19-4)
- IEC 60601-1-2:2014 (Fourth Edition) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (FDA recognition #19-8)
- ANSI AAMI ISO 10993-1:2018 (Fifth edition) Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (FDA recognition #2-258)

- ANSI AAMI IEC 62304:2016 Medical device software - Software life cycle processes [Including Amendment 1 (2016)] (FDA recognition #13-79)
- ISO 14971:2007 (Second edition) Medical devices - Application of risk management to medical devices) (FDA recognition #5-40)

J). Conclusion
The Plasmage is substantially equivalent to the predicate device.