February 29, 2024

Agnes Medical Co., Ltd
% Sanghwa Myung
Regulatory Affair Consultant
E&m
D-1474, 230, Simin-daero, Dongan-gu
Gyeonggi-do, Gyeonggi-do 14067
Korea, South

Re: K230837
Trade/Device Name: PlazMagik
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 2, 2024
Received: February 2, 2024

Dear Sanghwa Myung:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2024.02.29 14:11:05 -05'00'

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)*

Device Name
PlazMagik

Indications for Use *(Describe)*
PlazMagik is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

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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6. 510(k) Summary – Traditional 510(K)

The assigned 510(k) Number: K230837

01. Date of Submission: 2024.02.02

02. Applicant / Submitter

AGNES MEDICAL CO.,LTD
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03. Submission Correspondent

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04. Proposed Device Identification

Device Identification and Regulatory information

Proprietary Name: PlazMagik
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulation Number: 21 CFR 878.4400
Device Class: Class II
Product Code: GEI
Review Panel: General & Plastic Surgery

Indication for use: PlazMagik is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

05. Predicate Device Identification

Predicate device
510(k) Number: K201735
Device Name: Pladuo System
Manufacturer: ShenB Co. Ltd.

06. Device Description

The AGNES MEDICAL CO.,LTD PlazMagik is an electro-surgical device for use in dermatological applications. The effect of the device is achieved by heating the outer layer of the skin to that part or all or the epidermis becomes non-viable and there is controlled damage to the underlying dermis.

The PlazMagik system consists of a system console, footswitch, Two type of handpiece and tip guide.

07. Summary of Technological Characteristics Comparison

1) Predicate

	Subject Device	Predicate Device
Manufacturer	AGNES MEDICAL CO.,LTD	ShenB
Product Name	PlazMagik	PlaDuo System
510(k) Number	Not assigned	K201735
Product code /	GEI	GEI

Regulation	21 CFR 878.4400	21 CFR 878.4400
Classification	Class II	Class II
Indication for use	The PlazMagik is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	The Pladuo is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.
Mode of operation	Helium gas Argon gas	Nitrogen gas
Principal of operation	Plasma energy is delivered to the skin and energy is rapidly transferred to the skin surface. As the plasma energy passes through the tissue it generates an electrothermal reaction which is capable of coagulating tissue	Plasma energy is delivered to the skin and energy is rapidly transferred to the skin surface. As the plasma energy passes through the tissue it generates an electrothermal reaction which is capable of coagulating tissue
Frequency	24KHz	2.54GHz
Max Power (w)	Single H/P: 53.3W Triple H/P 34.13W	100 W
Repetition Rate	0.67Hz – 3Hz	1 - 3Hz
Emitting Time	100ms, 150ms, 166ms, 200ms, 250ms, 300ms, 400ms, 500ms, 1500ms	5 – 40ms
Gas requirement	Medical grade Helium / Medical grade Argon	Medical grade Nitrogen
Electrical voltage	AC 100-240V 50/60Hz	AC 100-230V 50/60Hz

The subject devices are substantially equivalent to the predicate and reference devices with respect to indications for use, technology and construction. The differences between the predicate devices and the subject devices are minor and any risks have been mitigated through testing.
The PlazMagik and the predicate device have same indication for use, Technology, mechanism of actions, operational principles and performance for the proposed indications for use.

The non-clinical data for proposed device, including biocompatibility, bench testing, hardware, and software documentation shows that the device should perform as intended in the specified use. In addition, the Electromagnetic Compatibility and Electrical Safety testing shows that the device is safe

to use and meets requirement.

There are no significant differences between Subject device and the predicate devices (K201735) that would adversely affect the use of the product. It is substantially equivalent to this device in design, function, and technical characteristics standards. In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this

08. Non-clinical Testing Data

(1) Biocompatibility

Test type	Standard	Results
Cytotoxicity	ISO 10993-05:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	Pass
Sensitization	ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	Pass
Irritation or Intracutaneous Reactivity	ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Pass

(2) Electrical Safety and electromagnetic compatibility (EMC)

Electrical safety, EMC and device-related electrical safety for high frequency were conducted on the PlazMagik according to the following consensus standards:

- IEC 60601-1:2005, AMD1:2012, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60101-2-2:2017, 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
- IEC 60601-1-2:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic

(3) Software Verification and Validation Testing

Software verification and validation testing was conducted for the subject device, and documentation was provided in accordance with FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", May 11, 2005, commensurate with a moderate level of concern.

(4) Bench Testing

AGNES MEDICAL conducted bench testing to assure that the PlazMagik operates safely and within the predefined design specifications. Tested parameters included:

- Output Energy
- Durability of the tip

(5) Ex Vivo Study

Ex Vivo testing conducted on three types of tissue – Liver, skin and Muscle under GLP Thermal testing in accordance with FDA's "Guidance for Industry and FDA Staff: Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery", August 15, 2014

09. Clinical Testing

Clinical testing is not a requirement and has not been performed.

10. Substantial Equivalence Conclusion

The comparison between the subject devices and the predicate devices shows that the general information, some technical and material information are the same. Although there are some differences, the performance test reports are supported to the substantial equivalence of the subject device, the performance test reports are provided to demonstrate substantial equivalence of the

subject devices. Therefore, we conclude that the different characteristics do not raise different questions of safety and effectiveness, and thus the subject devices are substantially equivalent to the predicate devices.