October 24, 2023

ShenB Co Ltd
% Aubrey Thompson
Regulatory Consultant
Hoy and Associates Regulatory Consultants
1830 Bonnie Way
Sacramento, California 95825

Re: K232223
Trade/Device Name: PlaDuo System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 26, 2023
Received: July 26, 2023

Dear Aubrey Thompson:

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: 2023.10.24 15:45:03 -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)*
K232223

Device Name
PlaDuo System

Indications for Use *(Describe)*
The PlaDuo is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The Argon handpiece is intended for the removal and destruction of skin lesions and the 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

This 510(K) Summary of safety and effectiveness for the PlaDuo System is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant	ShenB Co., Ltd.
Address	Shenb Bldg 148, Seongsui-ro Seongdong-Gu, Seoul, 04796 Republic of Korea
Contact Person	Aubrey Thompson, Regulatory Consultant
Contact Information	aubreythompson@hoyregulatory.com (323)533-8994
Preparation Date	July 26, 2023
Device Trade Name	PlaDuo System
510(k) number	K232223
Classification Name	Electrosurgical Cutting and Coagulation Device and Accessories
Regulation Number	878.4400
Product Code	GEI
Regulatory Class	II
Legally Marketed Predicate Device	Pladuo System (K201735)
Legally Marketed Reference Device	Subnovii Advanced Plasma Technology (K201738)

Device Description:
The PlaDuo System is an electro-surgical device for use in dermatological applications. The device utilizes nitrogen and argon gas to be used separately to generate the desired power level to patients. The effect of the device is achieved by heating the outer layer of the skin so that part or all of it becomes non-viable and there is controlled damage to the underlying skin.

The PlaDuo system consists of a system console with wells for 2 gas tanks, footswitch, 2 handpieces, and tip with 3 interchangeable guides.

Indications for use:

The PlaDuo is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The Argon handpiece is intended for the removal and destruction of skin lesions and the coagulation of tissue.

Substantial Equivalence—Indications for Use Comparison:

	Proposed Device PlaDuo	Predicate Device PlaDuo	Reference Device SubNovii	Comparison
Indications for Use	The PlaDuo is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The Argon handpiece is intended for the removal and destruction of skin lesions and the coagulation of tissue.	The PlaDuo is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	The SubNovii is used in the removal and destruction of skin lesions and the coagulation of tissue.	The proposed PlaDuo device shares the indications for use with its previous generation device. The addition of the argon handpiece adds the indications that are identical to the Subnovii device.

Substantial Equivalence –Technical Specifications Comparison:

	Proposed Device ShenB PlaDuo	Predicate Device ShenB PlaDuo	Reference Device Subnovii	Comparison
Mode of operation	Plasma Radiofrequency energy ionizes the air creating a Plasma stream	Plasma Radiofrequency energy ionizes the air creating a Plasma stream	Plasma Radiofrequency energy ionizes the air creating a Plasma stream	Same
Electrical Voltage	AC 100-230V/ 50/60Hz	AC 100-230V/ 50/60Hz	110-250 VAC 50/60 Hz	Same
Output Energy	Nitrogen Gas: 0.5 – 4J Argon Gas: 0.12J – 0.7J	Nitrogen Gas: 0.5 – 4J	5J	Same for Nitrogen, No argon option on predicate. See discussion below for Reference device power level difference.
Power Consumption	1000 VA	1000 VA	Not listed	Same for Predicate 1
Repetition Rate	1 – 3 Hz	1 – 3 Hz	N/A	Same for Predicate 1
Emitting Time	Nitrogen: 5 – 40ms +/- 20% Argon: 4-18ms	Nitrogen: 5 – 40ms	N/A	Same for Predicate 1. The pulse width is lower with the Argon because of the low discharge efficiency

				of argon and the potential for the build up of heat in the device with a longer pulse width.
Gas Requirement	Medical Grade Argon and Medical Grade Nitrogen	Medical Grade Nitrogen	Air	Different. The predicate device uses Nitrogen gas exclusively. The subject device adds argon. The reference device does not use a medical grade gas for plasma generation.

Performance Testing
Verification and validation activities were successfully completed and establish that the PlaDuo System control unit performs as intended. Testing included the following:

- IEC 60601-1:2005 + A1:2012; Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- IEC 60601-1-2:2014; 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;
- IEC 62304:2006+A1:2015; Medical Device – Software Life Cycle Processes;
- EN ISO 14971:2012; Medical Devices – Application Of Risk Management To Medical Devices

Biocompatibility –The only patient contacting material in the device are the space guides attached to each handpiece. Biocompatibility testing for cytotoxicity, irritation, and sensitization per ISO 10993-1:2018 are included with the submission and show now concern for patient contacting materials.

Software verification and validation testing was conducted, and documentation provided in accordance with FDA's Guidance or the Content of Premarket Submissions for Software Contained in Medical Devices.

In addition, thermal testing on ex vivo tissue specimens was conducted to verify the performance of the argon gas used with the device. The Test device at stacked pulses produced measurable thermal damage in skin and in liver models and traceable thermal effect in muscle. The study demonstrated the ability of the device to achieve consistent thermal damage profiles in line with the target treatment and comparable to the profiles produced by the predicate and reference devices. Thus, it can be concluded that treatment by such a device at the appropriate testing settings will possess a desirable clinical treatment effect.

Conclusion

The PlaDuo System that is the subject of this application is a next-generation of the currently cleared PlaDuo with Nitrogen only. Besides the addition of the gas and handpiece tip for use with Argon, there have been no changes to the device. Performance testing shows that the newly added argon feature produces consistent thermal damage profiles similar to predicate and reference devices. The subject device is substantially equivalent to the predicate device for the requested indications for use.