December 14, 2020

ShenB Co. Ltd.
% Connie Hoy
Consultant
Hoy and Associates
3916 N. Potsdam Ave #4676
Sioux Falls, South Dakota 57104

Re: K201735
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: November 29, 2020
Received: December 1, 2020

Dear Connie Hoy:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K201735

Device Name

PlaDuo System

Indications for Use *(Describe)*

The PlaDuo 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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510k SUMMARY

A summary of 510k safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

K201735

807.92(a)(1) - Submitter Information	
Name	ShenB Co Ltd.
Address	Shenb Bldg 148 Seongsui-ro Seongdong-Gu, Seoul , KR 04796
Phone number	82 70.4912.2702
Email	oskar@shenb.com
Establishment Registration Number	3010226575
Name of contact person	Mr. Oskar Lee
Date prepared	June 15, 2020
807.92(a)(2) - Name of device	
Trade or proprietary name	PlaDuo System
Common or usual name	Electrosurgical, cutting and coagulation device and accessories
Classification name	Electrosurgical, cutting and coagulation device and accessories
Classification panel	General and Plastic Surgery
Regulation	21 CFR 878.4400
Product Code(s)	GEI
Regulatory Class	Class II Prescription Use
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
Predicate device Reference device	Potenza (K)192545 Rhytec Portrait PSR (K)060948
807.92(a)(4) - Device description	
	The ShenB Co Ltd PlaDuo 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 so that part or all of the epidermis becomes non-viable and there is controlled damage to the underlying dermis. The PlaDuo system consists of a system console, footswitch, handpiece, and tip with 3 interchangeable guides.
807.92(a)(5) Intended use of the device	
Indications for use	The PlaDuo is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate			
Characteristic	Proposed Device PlaDuo System	Predicate Device Potenza (K)192545	Reference Device Rhytec Portrait PSR3 (K)060948
Mode of Operation	Nitrogen Gas	Radio Frequency	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.	RF energy is delivered through the skin into the target tissue via a handpiece equipped with an electrode tip. As the RF energy passes through the tissue, it generates an electrothermal reaction which is capable of coagulating the 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	2.45Ghz	1mHz and 2mHz	2.45Ghz
Max Power (w)	100W	50W	100W
Output Energy	0.5 – 4J	Up to 2J	1 – 4J
Repetition Rate	1 – 3 Hz	N/A	1 – 4 Hz
Emitting Time	5 – 40ms	N/A	5 – 40ms
Depth of thermal effect	up to 400 microns	Up to 4mm	Unknown
Gas Requirement	Medical Grade Nitrogen	N/A	Medical Grade Nitrogen
Electrical Voltage	AC 100-230V/ 50/60Hz	AC 100-230V/ 50/60Hz	AC 100-240V/ 50/60Hz

807.92(b)(1) NONCLINICAL TESTS SUBMITTED	
Discussion of nonclinical tests:	**Biocompatibility** ShenB performed biocompatibility testing for the electrode tips according to FDA's "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process'", June 6, 2016. Of the PlaDuo components, only the handpiece guide comes in contact with the patient. The handpiece guide is a surface device which comes in contact with skin a limited period of time, i.e., less than 24 hours. The electrode tips were tested as shown in the

table below:

Test Type	Standard	Results
Cytotoxicity	ISO 10993-05:2009, Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity	Pass
Sensitization: Guinea Pig Maximization Test (GPMT)	ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Pass
Irritation or Intracutaneous Reactivity [Animal Intracutaneous (Intradermal) Reactivity Test	ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Pass

Electrical Safety and electromagnetic compatibility (EMC)

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

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2-12, Medical electrical equipment – Part 1-2: 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 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and Tests

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.

	Bench Testing ShenB conducted bench testing to assure that the PlaDuo operates safely and within the predefined design specifications. Tested parameters included: • Output Energy • Durability of the tip • Thermal testing in accordance with FDA's "Guidance for Industry and FDA Staff: Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery"

807.92(b)(2) CLINICAL TESTS SUBMITTED

No Clinical study was conducted as part of this submission.

807.92(b)(3) Conclusion

The substantial equivalence of the PlaDuo is demonstrated through performance testing.

The PlaDuo has equivalent intended use, indication for use and thermal characteristics to the predicate device.

No new questions of safety and/or effectiveness are raised as a result of the differences when compared to predicate device based on the data provided in the submission. Therefore, the PlaDuo is substantially equivalent to the legally marketed predicate device.