January 22, 2021

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

Re: K202415
Trade/Device Name: VirtueRF
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)*
K202415

Device Name

VirtueRF

Indications for Use *(Describe)*

The VirtueRF Electrosurgical System has separate indications for use for each of its functionalities: 1MHz and 2MHz.

1MHz Indications for use

Intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis, and the percutaneous treatment of facial wrinkles. The VirtueRF Electrosurgical System is intended for use with Skin Types I-V.

2MHz Indications for use

Intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The 2mHz frequency is not intended to treat wrinkles.

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.

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."

510K Summary
K202415

This 510(K) Summary of safety and effectiveness for the VirtueRF 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.
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Contact Person:	Mr. Oskar Lee
Telephone:	82 70.4912.2702 – phone oskar@shenb.com
Preparation Date:	January 22, 2021
Device Trade Name:	VirtueRF
Common Name:	Electrosurgical, cutting & coagulation & accessories
Regulation Name:	Electrosurgical cutting and coagulation device and accessories
Regulation Number:	21 CFR 878.4400 (Product Code: GEI)
Legally Marketed Predicate Device:	Vivace Electrosurgical System K150409
Legally Marketed Reference Device:	Secret RF K182355
Regulatory Class:	Class II Prescription Use
Description of the VirtueRF :	The VirtueRF device is a radio frequency output device using 1MHz & 2Mhz to deliver radio frequency energy to the human body with an applicator attached to the connecting cable. The energy is applied to the human body using a sterile disposable needle array consisting of 36 needles. This product consists of main body, Needle Bipolar RF (Smart RF) handpiece cable, foot switch and power cord.
Intended use of VirtueRF :	The VirtueRF Electrosurgical System has separate indications for use for each of its functionalities: 1MHz and 2MHz. 1MHz Indications for use: Intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis, and the percutaneous treatment of facial wrinkles. The VirtueRF Electrosurgical System is intended for use with Skin Types I-V.

2MHz Indications for use: Intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The 2mHz frequency is not intended to treat wrinkles.

Performance Testing:

The following performance data was provided in support of the substantial equivalence determination:

IEC 60601-1 Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance;

IEC 60601-1-2 Test for Medical Equipment for General Requirements for basic safety and essential performance: electromagnetic compatibility

IEC 60601-2-2 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 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Thermal Effect Tests on 4 types of tissues (liver, kidney, muscle and skin) per FDA guidance Premarket Notification (510(K)) Submissions for Electrosurgical Devices for General Surgery. Test shows that the VirtueRF is substantially equivalent to the predicate device.

Technical Specifications / Indications for Use Comparison:

Comparison for 1MHz Functionality			
	Proposed Device ShenB VirtueRF	**Predicate device for 1MHz Vivace Electrosurgical System**	**Comparison**
Source of energy/Modality	Bipolar Fractional RF	Bipolar Fractional RF	Same
Radiofrequency	1MHz	1MHz	Same
Output energy type	High Frequency	High Frequency	Same
Electrode type	Bipolar microneedle	Bipolar microneedle	Same
Max Power	35.9W	61 w	Same
RF Duration	100ms-800ms, with 100ms increments	100ms-800ms, with 100ms increments	Same

Comparison for 2MHz Functionality			
	Proposed Device ShenB VirtueRF	**Reference device for 2MHz Secret RF**	**Comparison**
Source of Energy/Modality	Bipolar Fractional RF	Bipolar Fractional RF	Same
Radiofrequency	2MHz	2MHz	Same
Output energy type	High Frequency	High Frequency	Same
Electrode type	Bipolar microneedle	Bipolar microneedle	Same
Max Power	25 W	25W	Same
RF Duration	100ms-800ms, with 100ms increments	50ms – 950ms	Similar

Conclusion: The VirtueRF and the predicate device relevant to 1MHz functionality, the Vivace Electrosurgical System, have the same indications for use and the same technological characteristics. The VirtueRF and the reference device relevant to 2MHz functionality, the Secret RF, have the same indications for use and nearly identical technological characteristics. The RF duration for the proposed VirtueRF (100ms-800ms) varies from the Secret RF only in that it is a subset of the Secret RF Duration. Therefore, VirtueRF substantially equivalent to both the predicate device and the reference device and there are no new questions of safety or effectiveness.