November 23, 2021

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

Re: K211562
Trade/Device Name: Virtue RF
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 19, 2021
Received: October 20, 2021

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.
for 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)*
K211562

Device Name

Virtue RF

Indications for Use *(Describe)*

The Virtue RF System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

Smart RF Handpiece:
The Smart RF Handpiece with 1MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis, and the percutaneous treatment of facial wrinkles. The VirtueRF Electrosurgical System for facial wrinkles is intended for use with Skin Types I-V.

The Smart RF Handpiece with 2MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The with 2MHz functionality is not intended to treat wrinkles.

Exact RF Handpiece:
The Exact RF Handpiece with 1MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The Exact RF Handpiece is not intended to treat wrinkles.

Deep RF Handpiece:
The Deep RF Handpiece with 1MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The Deep RF handpiece with 1MHz functionality is not intended to treat wrinkles.

The Deep RF Handpiece with 2MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The Deep RF handpiece with 2MHz functionality is not intended to treat wrinkles.

The Deep RF Handpiece with 0.5MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The Deep RF handpiece with 0.5MHz functionality 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.

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510K Summary
Virtue RF K211562

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.
Address:	Shenb Bldg 148 Seongsui-ro Seongdong-Gu, Seoul , KR 04796
Contact Person:	Bora Kim
Contact Information:	kimbora@shenb.com +82-70-4814-2978
Preparation Date:	November 18, 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:	Virtue RF System K202415
Legally Marketed Reference Device:	Primaeva Medical Miratone System K082391 Agnes K192728
Regulatory Class:	Class II Prescription Use
Description of the VirtueRF :	The VirtueRF device is a radio frequency output device using 0.5MHz, 1MHz & 2Mhz to deliver radio frequency energy to the human body with 3 applicators that attach to the connecting cable. The energy is applied to the human body using sterile disposable needle arrays consisting of 36 needles, 12 needles, or 1 needle. This product consists of main body, SmartRF Bipolar handpiece, DeepRF Bipolar handpiece, ExactRF Monopolar handpiece, connector cable, grounding plate for ExactRF, cooling plate for the DeepRF, foot switch and power cord.

Intended use / Indication for Use of Virtue RF :

The Virtue RF System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

Smart RF Handpiece:
The Smart RF Handpiece with 1 MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis, and the percutaneous treatment of facial wrinkles. The VirtueRF System for facial wrinkles is intend for use with Skin types I-V.

The Smart RF Handpiece with 2 MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The Smart RF with 2MHz functionality is not intended to treat wrinkles.

Exact RF Handpiece:
The Exact RF Handpiece with 1MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The Exact RF Handpiece is not intended to treat wrinkles.

Deep RF Handpiece:
The Deep RF Handpiece with 1MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The Deep RF handpiece with 1MHz frequency is not intended to treat wrinkles.

The Deep RF Handpiece with 2MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The Deep RF handpiece with 2MHz frequency is not intended to treat wrinkles.

The Deep RF Handpiece with 0.5MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The Deep RF handpiece with 0.5MHz 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.

Comparison to the predicate and reference devices:

Comparison for Smart RF handpiece - 1MHz functionality			
	Proposed Device ShenB VirtueRF	**Predicate device for 1MHz Virtue RF K202415**	**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	35.9 W	35.9 W	Same
RF Duration	100ms-800ms, with 100ms increments	100ms-800ms, with 100ms increments	Same

Comparison for Smart RF Handpiece - 2MHZ Functionality			
	Proposed Device ShenB VirtueRF Smart RF Handpiece	**Predicate Device Virtue RF K202415**	**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	100ms-800ms, with 100ms increments	Same

Comparison for ExactRF Handpiece				
	Proposed Device Virtue RF Exact RF Handpiece	**Predicate Device Virtue RF K202415**	**Reference Device Agnes K160469**	**Comparison**
Source of Energy/Modality	Monopolar	Bipolar	Monopolar	Similar; same as reference device
Radiofrequency	1MHz	1Mhz & 2MHz	1MHz	same
Electrode type	Monopolar single needle RF electrode	Bipolar microneedle	Monopolar single needle RF electrode	Similar; same as reference device
Number of Needles	1	36	1	Different; same as reference device
Grounding Mechanism	Electrode plate	N/A	Disposable neutral electrode pad	Similar to reference device
Max Power	46W	35.9W	46W at 200Ω	Same as reference; similar to predicate device
RF Duration	100ms-800ms, with 100ms increments	100ms-800ms, with 100ms increments	50ms - 2,000ms	Same; similar to reference device

Comparison for DeepRF Handpiece – 1MHz & 2MHz Functionality			
	Proposed Device Deep RF Handpiece- 1MHz	**Predicate Device Virtue RF - 1MHz K202415**	
Source of Energy/Modality	Bipolar	Bipolar	Same
Radiofrequency	1MHz	1MHz	Same
Electrode type	Bipolar microneedles with RF Electrode	Bipolar microneedles with RF Electrode	Same
Max Power	155 W at 500Ω	35.9W	Different
RF Duration	100ms-800ms, with 100ms increments	100ms-800ms, with 100ms increments	Same

	Proposed Device – Deep RF – 2MHz	**Predicate Device Virtue RF – 2MHz K202415**	
Source of Energy/Modality	Bipolar	Bipolar	Same
Radiofrequency	2MHz	2MHz	Same
Electrode type	Bipolar microneedles with RF Electrode	Bipolar microneedles with RF Electrode	Same
Number of Needles	12 or 36	36	Similar
Max Power	60W	35.9W	Similar
RF Duration	100ms-800ms, with 100ms increments	100ms-800ms, with 100ms increments	Same

Comparison for DeepRF Handpiece - 0.5MHz Functionality				
	Proposed Device – Deep RF 0.5MHz	**Predicate Device Virtue RF**	**Reference Device Primaeva K082391**	**Comparison**
Source of Energy/Modality	Bipolar	N/A. Approved Virtue does not have 0.5MHz functionality	Bipolar	Same
Radiofrequency	0.5MHz	N/A	.46MHz	Similar
Electrode type	Bipolar Handpiece + Micro needle electrodes	N/A	Bipolar Handpiece + Micro needle electrodes	Same
Number of Needles	12 or 36	N/A	10 (3 different tips all with 10 needles)	Similar
Max Power	220W	N/A	25W	Different
RF Duration	100~800ms and can be adjusted 100ms	N/A	Adjustable 10-50 ms on for every 100 ms	Same
Cooling Modality	Detachable TEC Cooling plate. Water cooling system inside handpiece controls and maintains temperature of cooling plate.	N/A	Cooler controller and reusable cooler controller handpiece/applicator	Similar

Conclusion: The proposed VirtueRF is the same system as the FDA cleared VirtueRF (K202415) and adds 2 additional handpieces, each with their own disposable cartridges. The indications for use and the technological characteristics are the same as the predicate device and the reference devices. Substantial equivalence is supported by the performance testing and there are no new questions of safety or effectiveness.