September 25, 2024

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

Re: K241535
Trade/Device Name: Vybe RF II
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 27, 2024
Received: August 27, 2024

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.09.25 07:42:48 -04'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241535

Device Name
VYBE RF II

Indications for Use *(Describe)*
The VYBE RF II is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

Microneedle Array Handpiece (1MHz): The Microneedle Array Handpiece with 1 MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. At power less than 36W, the Microneedle Array Handpiece with 1 MHz functionality is intended for the percutaneous treatment of facial wrinkles in Skin Types I-V.

Microneedle Array Handpiece (2MHz): The Microneedle Array Handpiece with 2 MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The Microneedle Array handpiece with 2MHz functionality is not intended to treat wrinkles.

One Pin Exact Handpiece: The One Pin Exact handpiece with 1MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The One Pin Exact Handpiece 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary
Vybe RF II System
K241535

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
Preparation Date	September 24, 2024
Device Trade Name	Vybe RF II
Classification Name	Electrosurgical Cutting and Coagulation Device and Accessories
Regulation Number	878.4400
Product Code	GEI
Regulatory Class	II
Legally Marketed Predicate Devices	Virtue RF (K211562) Vybe RF (K230986)

Device Description:
VYBE RF II is a High Frequency Electrosurgical Unit that uses electrical currents to coagulate tissue. The device consists of the device console, Microneedle Array Handpiece, One Pin Exact Handpiece, RF plate, Foot Switch, and Power Cord. VYBE RF II is operated through an intuitive user interface (UI) on a 10.4- inch wide touch LCD screen. This product delivers high-frequency energy to the human body through the needle tip cartridge connected to the Microneedle Array Handpiece (1MHz, 2MHz) and One Pin Exact Handpiece (1MHz).

Indications for use:

The VYBE RF II is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

Microneedle Array Handpiece:
Microneedle Array Handpiece (1MHz): The Microneedle Array Handpiece with 1 MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. At power less than 36W, the Microneedle Array Handpiece with 1 MHz functionality is intended for the percutaneous treatment of facial wrinkles in Skin Types I-V.

Microneedle Array (2MHz): The Microneedle Array Handpiece with 2 MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The Microneedle Array handpiece with 2MHz functionality is not intended to treat wrinkles.

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

510(K) Summary
Vybe RF II System
K241535

Substantial Equivalence—Indications for use and Technical Comparison

Specification	Vybe RF II (Subject Device)	Virtue RF (K211562)	Vybe RF (K230986)	Comparison
Product Code	GEI	GEI	GEI	Same
Operation	Radiofrequency Microneedling	Radiofrequency Microneedling	Radiofrequency Microneedling	Same
# of needles	36 needle tip, 1 needle tip	36, 12, and 1 needle tips	36 needle tip	The 36 and 1 needle tips are identical to those used in the Virtue RF. The 12 needle tip in the Virtue RF is not included in Vybe RF II. The reference device, K230986, includes only a 36 needle tip.
Frequency	2MHz, 1MHz	2MHz, 1MHz, 0.5Mhz	2MHz, 1MHz	The 0.5 MHz frequency of the Virtue RF corresponds to the 12 needle tip and is not included in Vybe RF II.
Modality	Monopolar and Bipolar	Monopolar and Bipolar	Bipolar	Same as predicate. Reference device contains only bipolar.
Indications	The VYBE RF II is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. Microneedle Array Handpiece (1MHz): The Microneedle Array	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	The VYBE RF Electrosurgical System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis and the percutaneous treatment facial wrinkles for use with Fitzpatrick Skin Type I to Skin Type V when using the	Same. The Virtue RF includes additional indications for the Deep RF handpiece, which is not included in this submission. The indications for use for the subject device specifies the power level under which the wrinkles indication is allowable.

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Vybe RF II System
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	Handpiece with 1 MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. At power less than 36W, the Microneedle Array Handpiece with 1 MHz functionality is intended for the percutaneous treatment of facial wrinkles in Skin Types I-V. Microneedle Array (2MHz): The Microneedle Array Handpiece with 2 MHz functionality is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. The Microneedle Array handpiece with 2MHz functionality is not intended to treat wrinkles.	dermatologic and general surgical procedures for electrocoagulation and hemostasis, and the percutaneous treatment of facial wrinkles. The VirtueRF System for facial wrinkles is intended 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.	1MHz setting. The 2MHz setting has not been evaluated for use in the percutaneous treatment of facial wrinkles and is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	

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

Microneedle Array Handpiece Comparison				
Specification	Subject Device – VYBE RF II Microneedle Array HANDPIECE (SH-TIP)	Predicate Device - Virtue RF SMART RF HANDPIECE	Reference Device – VYBE RF	Comparison
Modality	Bipolar fractional RF	Bipolar fractional RF	Bipolar fractional RF	Same
Radiofrequency	1MHz, 2MHz	1MHz, 2MHz	1MHz, 2MHz	Same
Electrode Type	Bipolar microneedle	Bipolar microneedle	Bipolar microneedle	Same
Number of needles	36	36	36	Same
Max power	59 W @ 1 MHz 30 W @ 2MHz	35.9 W @ 1 MHz 25 W @ 2MHz	59W	Different. The max power output is higher for the subject device than for the predicate. See discussion below.
RF Duration	100ms-800ms, with 100ms increments	100ms-800ms, with 100ms increments	100ms-800ms, with 100ms increments	Same

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Microneedle depth	Max 3.5mm	Max 3.5mm	Max 3.5mm	Same

One Pin Exact Handpiece Comparison				
Specification	Subject Device – VYBE RF II ONE PIN EXACT HANDPIECE	Predicate Device - Virtue RF EXACT RF HANDPIECE	Reference Device – VYBE RF	Comparison
Modality	Monopolar Fractional RF	Monopolar Fractional RF	N/A	Same
Radiofrequency	1 MHz	1 MHz	N/A	Same
Electrode Type	Monopolar single needle RF electrode	Monopolar single needle RF electrode	N/A	Same
Number of needles	1	1	N/A	Same
Max power	46 W	46 W	N/A	Same
RF Duration	100ms-800ms, with 100ms increments	100ms-800ms, with 100ms increments	N/A	Same
Grounding Mechanism	Disposable Neutral electrode pad	Neutral electrode plate	N/A	Different. The grounding mechanism is the same, the materials and reuse are different.

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Performance Testing
Verification and validation activities were successfully completed and establish that the Vybe RF II 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
- IEC 60601-1-6:2010, AMD1:2013, AMD2:2020- Medical Electrical Equipment Part 1-6: General requirements for safety- collateral standard: Usability

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.

Bench testing was performed to verify the accuracy of the output of RF energy. Histopathology testing was conducted to demonstrate the thermal effect of the device. A test summary is provided below.

Histopathology Testing Summary
In vitro testing of the VYBE RF II Radiofrequency Microneedling device (Test Device), equipped with VYBE RF Microneedle Array handpiece (HP) and SH-TIP cartridges, and operated at 1 and 2 MHz frequencies was performed. Testing was performed on three different types of tissue recommended by the FDA: *ex vivo* kidney (bovine), liver (bovine), and skin (Yucatan mini-pig, abdomen site). "FDA guidance for Industry for Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery" recommends conducting testing at minimum, medium (default), and maximum (highest) power settings. The Test Device can be operated at two different frequencies 1- and 2 MHz. It is also operated at power levels from 1 to 10 with level 1 as the minimum and 10 maximum (highest) power level for both frequencies. Therefore, testing was performed at levels 1, 5, and 10 for both frequencies with the longs pulse width available on the device to demonstrate a 'worst case.'

The study demonstrated the ability of the Test Device to achieve consistent thermal damage profiles in line with the target treatment. Thus, it can be concluded that treatment by such a device at the appropriate testing settings will possess a desirable clinical treatment effect.

Clinical Evidence – N/A. No clinical studies were conducted as part of this submission.

Biocompatibility – Patient contacting materials have been determined to be biocompatible.

510(K) Summary
Vybe RF II System
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Discussion

The VYBE RF II shares the same indications for use, technological characteristics, and handpieces as the Predicate device, the Virtue RF System. The main difference between the two devices is the maximum power achieved with the 36 needle handpiece and disposable tip. The Vybe RF II has a higher maximum power while using the same 36 needle tip, but the same power level as the reference device (the previously cleared Vybe RF). The single needle tip is identical to the predicate device except for the type of neutral electrode used. Thermal testing, biocompatibility testing, essential performance testing, and IEC testing demonstrate the VYBE RF II is safe and effective and can be considered substantially equivalent to the predicate device.