July 6, 2023

ShenB Co Ltd
% Connie Hoy
Consultant
Hoy and Associates
1830 Bonnie Way
Sacramento, California 95825

Re: K230968
Trade/Device Name: VYBE RF Electrosurgical System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 12, 2023
Received: June 12, 2023

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.07.06 14:32:19 -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)*
K230968

Device Name
VYBE RF Electrosurgical System

Indications for Use *(Describe)*

The VYBE RF Electrosurgical System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis and the percutaneous treatment of facial wrinkles for use with Fitzpatrick Skin Type I to Skin Type V when using the 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.

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.

510(k) Summary

VYBE RF

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR Part 807.92.

A. SPONSOR INFORMATION

Name: ShenB Co., Ltd.
Address: Shenb Bldg 148, Seongsui-ro
Seongdong-Gu, Seoul, 04796
Republic of Korea
Phone: 82-2-466-0010
Fax: 82-2-466-5473

Official Correspondent:

Name: Connie Hoy
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1830 Bonnie Way
Sacramento, CA 95825
Phone: 530-908-4903
Email: conniehoy@hoyregulatory.com

Establishment Reg. No.: 3010226575

Date Prepared: June 12, 2023

B. DEVICE NAME

Trade Name:	VYBE RF Electrosurgical System
Common Name:	Electrosurgical System and Accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Number:	21 CFR 878.4400 (Class II)
Product Code:	OUH
Classification Panel:	General and Plastic Surgery

C. PREDICATE DEVICE

The VYBE RF Electrosurgical System is substantially equivalent to the VIVACE Electrosurgical System (K193070). Both the subject device (VYBE RF) and the predicate device (VIVACE) are manufactured by ShenB Co., Ltd.

D. INDICATIONS FOR USE

The VYBE RF Electrosurgical System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis and the percutaneous treatment of facial wrinkles for use with Fitzpatrick Skin Type I to Skin Type V when using the 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.

E. DEVICE DESCRIPTION

The VYBE RF Electrosurgical System is comprised of the following components:

- The system main body, consisting of:
  - LCD touch screen control panel
  - High-frequency generating output section (main P.C.B board or RF Generator)
  - Power supply component - Switch Mode Power Supply (SMPS)
- The accessories to the device include:
  - Handpiece with Handpiece Connector
  - Disposable micro-needle cartridge (electrode) for insertion into Handpiece
  - Foot switch

Radio frequency current (RF energy) is delivered from the RF Generator, through the handpiece and electrode tip into the target tissue. As RF energy passes through the skin, it generates an electro thermal reaction, which is capable of coagulating (causing minor dermal damage) the tissue. The bi-polar RF energy is delivered between independent adjacent electrode pairs (total 36 needle electrode, 6 x 6 array insertion). The RF generator and hand piece are not disposable. Each disposable micro-needle cartridge (electrode) is supplied sterile and is for single patient use only and cannot be re-sterilized.

F. TECHNOLOGICAL SPECIFICATIONS

The VYBE RF Electrosurgical System is substantially equivalent to the noted predicate devices, with respect to technological characteristics, such as intended use, principles of operation, target population, and energy source.

Electrical voltage and frequency		AC 120V 50/60 Hz
Power conception		180 VA
Maximum Power		59W ± 10% (load resistance 500Ω)
Frequency		1 MHz, 2 MHz
Microneedle Cartridge	Electrode	36 each, 6 x 6 array
	Exposed length	0.5 ~ 3.5mm (0.1mm increments)
	Outer diameter	Ø 0.3mm
Dimensions		(W)380mm x (L)340mm x (H)1200mm

G. PERFORMANCE DATA

To establish safety and efficacy of the VYBE RF Electrosurgical System, the following evaluations were completed following standards and FDA guidance documents. All acceptance criteria were met:

- **Electrical Testing per:**
  - IEC 60601-1:2005/(R)2012, A1:2012
  - IEC 60601-1-2:2014, Ed. 4.0
  - IEC 60101-2-2:2017, Ed. 6.0
  - IEC 60601-1-6:2010 +A1 2013
  - IEC 62366:2007/AMD 1:2014
- **Biocompatibility Testing per:**
  - ISO 10993-1:2009
  - ISO 10993-5:2009
  - ISO 10993-10:2010

- **Sterility Testing:**
  - The micro-needle cartridge is supplied sterile and sterility conforms to a Sterility Assurance Level (SAL) of 10^{-6}:
    - ISO 11135:2014
    - ISO 11138-1:2017
    - ISO 11138-2:2017
    - ISO 11737-1:2018
    - ISO 11737-2:2019
    - ISO 10993-7:2008
- **Software Verification and Validation Testing:**
  - Software verification and validation testing were conducted as recommended by FDA's Guidance for Industry and FDA Staff, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices",* issued May 11, 2005.
- **Thermal Testing:**
  - Testing of the thermal effects on tissue was completed in accordance with FDA's Guidance for Industry and FDA Staff *"Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery"*, issued March 9, 2020.

H. Comparison to the Predicate Device

Device name	VYBE RF (Subject Device)	PREDICATE VIVACE (K193070)	Comparison
Manufacturer	ShenB Co., Ltd.	ShenB Co., Ltd.	**SAME**
Classification # & Product Code	878.4400 OUH, GEI	878.4400 OUH	**SAME**
Indication for Use	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 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.	The VIVACE 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 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.	SAME

Device name	VYBE RF (Subject Device)	PREDICATE VIVACE (K193070)	Comparison
Source of Energy	Bipolar Fractional RF	Bipolar Fractional RF	**SAME**
Delivery system	Bipolar Handpiece + Micro needle electrodes	Bipolar Handpiece + Micro needle electrodes	**SAME**
RF Frequency	1MHz (±10%)	1MHz (±10%)	**SAME**
	2MHz (±10%)	2MHz (±10%)	
Max power	1MHz: 36 W (Load resistance 500Ω)	1MHz: 36 W (Load resistance 500Ω)	**SAME**

I. CONCLUSION

The subject VYBE RF Electrosurgical System is identical to the Vivace Electrosurgical device. The only difference is the packaging for the sterile disposable tip has been changed to a blister pak with Tyvek. This change does not raise any new concerns for the safety or effectiveness of the device.