



April 26, 2021

ShenB Co Ltd.
% Rachel Lord
Director RA/QA
Aesthetics Biomedical
4602 N 16th St Suite 300
Phoenix, Arizona 85016

Re: K193070
Trade/Device Name: VIVACE Electrosurgical Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 3, 2021
Received: April 5, 2021

Dear Rachel Lord:

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

Indications for Use

510(k) Number (if known)
K193070

Device Name
Vivace Electrosurgical System

Indications for Use (Describe)

The VIVACE 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.

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510(k) Summary

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: Rachel Lord
Address: Aesthetics Biomedical
4602 North 16th Street, Suite 300
Phoenix, AZ 85016
Phone: (201) 841-7975
Email: rlord@aestheticsbiomed.com

Establishment Reg. No.: 3010226575

Date Prepared: April 2, 2020

B. DEVICE NAME

Trade Name:	VIVACE
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, GEI
Classification Panel:	General and Plastic Surgery

C. PREDICATE DEVICE

The VIVACE Electrosurgical System is substantially equivalent to the existing VIVACE Electrosurgical System (primary predicate), K150409. The Secret RF Device K170325 is the reference device to support the 2MHz functionality.

D. INTENDED USE

The VIVACE 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 VIVACE 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 VIVACE Electrosurgical System is substantially equivalent to the primary predicate device, 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		80 VA
Maximum Power		36W ± 10% (load resistance 500Ω)
Accuracy of the output		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 VIVACE 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

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- **Shelf Life and Packaging Testing per:**
 - ASTM F1980-16
 - ASTM F1929-15
 - ASTM F88/F88M-15
- **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.
 - The *ex vivo* animal study utilized a porcine tissue model and standardized H&E staining techniques to visualize and measure thermally damaged profile data through Nitro Blue Tetra Chlorine (NBTC) and H&E histological evaluation of VIVACE System treated tissue specimens. The VIVACE microneedling device showed consistent formation of measurable thermal lesions for highest energy level settings in the treatment porcine tissue at a temperature close to physiological.

H. SUMMARY OF SUBSTANTIAL EQUIVALENCE

The subject VIVACE Electrosurgical System is substantially equivalent to the primary predicate, the VIVACE Electrosurgical System (K150409). The Secret RF Device K170325 is the reference device to support the 2MHz functionality. The below table provides a comparison of the VIVACE technological characteristics to the predicate devices.

Device name	VIVACE (Subject Device)	PRIMARY PREDICATE VIVACE (K150409)	REFERENCE PREDICATE Secret RF (K170325)	Difference/Risks/Notes
Manufacturer	ShenB Co., Ltd.	ShenB Co., Ltd.	ILOODA CO., LTD	Different Manufacturer for Reference Predicate (Secret RF)
Classification # & Product Code	878.4400 OUH, GEI	878.4400 OUH	878.4400 GEI, OUH	NO DIFFERENCE
Indication for Use	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.	Intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis, and the percutaneous treatment of facial wrinkles. This Vivace Electrosurgical System is intended for use with Skin Type I to Skin Type V.	Secret RF is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.	NO DIFFERENCE
Source of Energy	Bipolar Fractional RF	Bipolar Fractional RF	Bipolar Fractional RF	NO DIFFERENCE
Delivery system	Bipolar Handpiece + Micro needle electrodes	Bipolar Handpiece + Micro needle electrodes	Bipolar Handpiece + Micro needle electrodes	NO DIFFERENCE
RF Frequency	1MHz (±10%)	1MHz (±10%)	N/A	<ul style="list-style-type: none"> • Additional (lower) frequency setting in comparison to existing VIVACE frequency • NO DIFFERENCE from Secret RF2 MHz frequency
	2MHz (±10%)	N/A	2MHz (±10%)	
Max power	1MHz: 36 W (Load resistance 500Ω)	1MHz: 61.5 W (Load resistance 500Ω)	N/A	<ul style="list-style-type: none"> • VIVACE has a slightly lower output as the predicate VIVACE, when using

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Device name	VIVACE (Subject Device)	PRIMARY PREDICATE VIVACE (K150409)	REFERENCE PREDICATE Secret RF (K170325)	Difference/Risks/Notes
	2MHz: 23.3 W (Load resistance 500Ω)	N/A	2 MHz: Max 25W± 10% (Load resistance 500Ω)	the 1 MHz setting. <ul style="list-style-type: none"> • VIVACE has a slightly lower output than the predicate Secret RF device, when using the 2 MHz setting.
Connected electrodes	36 Electrodes	36 Electrodes	MTR-AC-25 (25 Electrodes) or MTR-AC-64 (64 Electrodes)	<ul style="list-style-type: none"> • NO DIFFERENCE from existing Vivace device • Within Electrode Range of Secret RF device
User interface	LCD touch screen control panel	LCD touch screen control panel	LCD touch screen control panel	NO DIFFERENCE
Electrical Requirements	120VAC, 50/60Hz	120VAC, 50/60Hz	120VAC, 50/60Hz, 3-1A	NO DIFFERENCE
Intensity	1-10 Level (1 Step)	1-10 Level (1 Step)	0-10 Level (2/5/10 STEP)	<ul style="list-style-type: none"> • NO DIFFERENCE from existing Vivace device • NO DIFFERENCE in range of intensity levels from existing Secret RF device
Weight (Without Arm)	24kg	24kg	40kg	<ul style="list-style-type: none"> • NO DIFFERENCE from existing Vivace device • Lighter than Secret RF device
Needle insert depth	0.5 ~ 3.5mm (0.1mm step)	0.5 ~ 3.5mm (0.1mm step)	0.5~3.5mm (0.1 step)	NO DIFFERENCE

I. CONCLUSION

The subject VIVACE device, when used with the 2 MHz setting, is identical to the predicate and reference devices (K170325 and K150409) with respect to the principles of operation, technological characteristics, as well as performance characteristics. Non-clinical testing was conducted to evaluate the performance of subject device in comparison to the predicate devices and results have demonstrated substantial equivalence of the subject device to the predicates in terms of safety and effectiveness for the intended use.