April 1, 2020

Venus Concept USA Inc.
Yoni Iger
Vice President, QA/RA/CA
1880 N Commerce Pkwy, Suite 2
Weston, Florida 33326

Re: K191065
Trade/Device Name: Venus Viva Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 1, 2020
Received: March 4, 2020

Dear Yoni Iger:

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 on last page

510(k) Number *(if known)*
K191065

Device Name

Venus Viva™ Device

Indications for Use *(Describe)*

The Venus Viva™ Device is a non-invasive device intended to be used by aesthetic physicians or dermatologists.

When used with the Diamondpolar applicator, the Venus Viva™ Device is intended for use in dermatological and surgical procedures for females for the non-invasive treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin type I-IV.

When used with the Viva applicator, the Venus Viva™ Device is intended for use in dermatological procedures requiring ablation and resurfacing of the skin.

Type of Use *(Select one or both, as applicable)*

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

VENUS VIVA DEVICE

510(k) Number K191065

Applicant Name:

Company Name: Venus Concept USA Inc.

Address: 1880 N Commerce Pkwy, Suite 2

Weston, FL 33326

United States

Tel: +1-888-9070115

Fax: +-888-9070115

E-mail: Yoni@venusconcept.com

Contact Person:

Official Correspondent: Dr. Yoni Iger

Company Name: Venus Concept USA Inc.

Tel: +1-9545489312

E-mail: Yoni@venusconcept.com

Date Prepared: March 2020

Trade Name: Venus Viva ™ Device

Classification Name: Electrosurgical cutting and coagulation device and accessories

CFR Classification section 878.4400; (Product code GEI)

Classification: Class II Medical Device

Classification Panel: General & Plastic Surgery

Predicate Devices: Venus Viva ™ SR device (K150161)

Venus Legacy BX Device (K142910)

Intended Use/Indication for Use:

The Venus Viva™ Device is a non-invasive device intended to be used by aesthetic physicians or dermatologists.

When used with the Diamondpolar applicator, the Venus Viva™ Device is intended for use in dermatological and surgical procedures for females for the non-invasive treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin type I-IV.

When used with the Viva applicator, the Venus Viva™ Device is intended for use in dermatological procedures requiring ablation and resurfacing of the skin.

Device Description

The Venus Viva™ device consists of a console (main unit) and two applicators – Viva and Diamondpolar. The console contains a power supply unit, an RF generator (power module, on main board), a controller unit (on main board) and a touchscreen user interface and display panel.

The Venus Viva™ device is a combination of the previously cleared Venus Viva™ SR (K150161), the primary predicate, and the Diamondpolar applicator that was previously cleared for the secondary predicate Venus Legacy BX (K142910). Both the Viva and Diamondpolar applicators can now be connected simultaneously to a single console, the Venus Viva™ console.

Technological Characteristics:

The Venus Viva™ is a computerized system generating RF energy and Pulsed Magnetic Fields (PMF), which are emitted into the skin. RF energy heats the tissue to trigger collagen remodeling for treatment of wrinkles and rythides or for the ablation and resurfacing of the skin. The Venus Viva™ device combines the effects of RF energy and PMF to the selected applicator. The energies provide optimal treatment results with minimal risk of side effects.

Performance Data:

Venus Concept conducted several performance tests to demonstrate that the Venus Viva™ device complies with performance standards and that it functions as intended.

Performance Bench Testing: The Venus Viva™ device underwent performance testing, including software validation and device verification tests in order to evaluate the Venus Viva™ device's RF and PMF output parameters per specifications, and as compared to the predicate device's specifications. The results demonstrated that the Venus Viva™ device has the same RF and PMF output specifications and temperature stability profile as those reported for the predicate device and therefore, is substantially equivalent to the predicate device.

Electrical Safety and Electromagnetic Compatibility: In addition, the device was tested per the applicable electrical safety and electromagnetic compatibility standards listed below, and all results were passing:

- IEC 60601-1, (Ed. 3.1 ,2012): Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2, (Fourth Edition, 2014): Medical Electrical Equipment - Part 1-2 General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.
- IEC 60601-2-2, (Sixth Edition, 2017): Medical Electrical Equipment - Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.
- IEC 60601-1-6, (Third Edition, 2013): Medical Electrical Equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- IEC 62304, (Ed. 1.1, 2015): Medical device software - Software life cycle processes.

Software Testing: The software was also subjected to verification and validation testing, and results demonstrated that the system performed as intended.

These performance tests demonstrated that the device meets the system requirements and do not raise new types of safety or effectiveness concerns.

Sterilization and Cleaning

The Diamondpolar applicator of the Venus Viva™ device is not provided sterile, nor is it intended to be sterilized by the end user. Users are instructed to clean and disinfect the system components between use, per the directions provided in the User Manual.

The same cleaning and disinfection instructions were previously validated for the predicate device, the company's Venus Legacy BX (K142910).

The tip of the Viva applicator is for single use and has to be sterilized by autoclave prior to use. The tip is provided non-sterile and will be sterilized by the end user. The applicator tips are to be steam sterilized by autoclave per the validated parameters below:

Temperature: 121°C

Full cycle time: 30 minutes

Dry time: 15 minutes

The same steam sterilization instructions were previously validated for the predicate device, the company's Venus Viva ™ SR (K150161).

Biocompatibility

The Venus Viva™ system is a surface device in limited contact (<24 hours) with intact skin.

The patient-contacting parts/materials of the Venus Viva™ device are:

- Disposable tips of the Viva applicator. The tip consists of stainless steel pins sealed in a plastic base.
- Chrome-coated electrodes of the Diamondpolar applicator.

The patient-contacting components were tested for cytotoxicity, sensitization, and irritation or intracutaneous reactivity as defined for surface devices in the FDA guidance and ISO 10993-1. Based on results of the conducted testing all materials were determined biocompatible for their intended use.

Substantial Equivalence:

The following table compares the Venus Viva™ device to the predicate devices with respect to intended use, technological characteristics and principles of operation, providing detailed information regarding the basis for the determination of substantial equivalence.

Venus Concept, Ltd.'s Venus Viva™ Substantial Equivalence

	Venus Viva **Venus Concept Ltd.** **(K191065)**	**Venus Viva SR** **Venus Concept Ltd.** **(K150161)**	**Venus Legacy BX** **Venus Concept Ltd.** **(K142910)**
Class, Product Code, Regulation	Class II, GEI, 21 CFR 878.4400	Class II, GEI, 21 CFR 878.4400	Class II, GEI, 21 CFR 878.4400
Indications for Use	The Venus Viva™ Device is a non-invasive device intended to be used by aesthetic physicians or dermatologists. • When used with the Diamondpolar applicator, the Venus Viva™ Device is intended for use in dermatological and surgical procedures for females for the non-invasive treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin type I-IV. • When used with the Viva applicator, the Venus Viva™ Device is intended for use in dermatological procedures requiring ablation and resurfacing of the skin.	The Venus Viva SR is intended for dermatological procedures requiring ablation and resurfacing of the skin.	The Venus Legacy BX is a noninvasive device intended for use in dermatologic and general surgical procedures for females for the non-invasive treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin types I-IV.
Energy Used / Delivered	RF Energy Pulsed Magnetic Field (PMF)	RF Energy	RF Energy Pulsed Magnetic Field (PMF)

Applicator Footprint Dimensions	Viva : 1.33 cm^2 Diamondpolar: 2.9 cm^2	Viva SR: 1.33 cm^2	Diamondpolar: 2.9 cm^2
Performance	Frequency: 1MHz, 0.46 MHz Max. output energy for Viva Fractional applicator: 62 mJ/pin Maximal RF output power for Diamondpolar Applicator: up to 75W PMF Power: 15 Gauss (15Hz)	Frequency: 0.46 MHz Max. output energy for Viva SR applicator: 62 mJ/pin	Frequency: 1MHz Maximal RF output power for Diamondpolar Applicator: up to 75W PMF Power: 15 Gauss (15Hz)
Materials	Materials are biocompatible	Materials are biocompatible	Materials are biocompatible
Power requirements	100-240 VAC 50-60Hz	100-240 VAC 50-60Hz	100-240 VAC 50-60Hz

As described in the comparison table above, the Venus Viva™ device has the same intended use and a combination of the indications of the predicates previously cleared Venus devices. The device also has the same technological characteristics compared to the predicate devices.

The Venus Viva™ device is a modified device of the Venus Viva™ SR device, the primary predicate previously cleared under (K150161). The design and components in the Venus Viva™ device, including the console (with power supply, RF generator, controller and display panel) and the applicator (with cable and connector to console) are similar to the design and components found in the predicate Venus Viva™ SR device. The only modification between the Venus Viva™ SR device and the Venus Viva™ device is the integration of the Diamondpolar applicator in the Venus Viva™ device. The Venus Viva™ device is basically the same device as the Venus Viva™ SR device with the addition of the Diamondpolar applicator that was previously cleared for the co-primary predicate device Venus Legacy BX (K150161).

The safety features and compliance with safety standards in the Venus Viva™ device are similar to the safety features and compliance with safety standards found in both predicate devices. The patient contact materials are biocompatible in compliance with the ISO 10993 standard and similar to materials found in the predicate devices.

The cleaning and disinfection instructions for the Diamondpolar applicator are consistent with the previously validated for the predicate device, the company's Venus Legacy BX (K142910). The sterilization instructions for the tip of the Viva applicator are the same steam sterilization instructions that were previously validated for the predicate device, the company's Venus Viva™ SR (K150161).

In addition, the Venus Viva^{TM} device underwent performance testing, including software validation testing, electrical safety according to IEC 60601-1 and electromagnetic compatibility testing according to IEC 60601-1-2. These performance tests demonstrated that the specifications (including RF electrical power output and PMF output) of the Venus Viva^{TM} meet the system requirements and there are no new safety or effectiveness concerns.

Furthermore, the general method of treating the patient's skin, the levels of energies used in treatment of skin, the size of treatment area and treatment zone, the active electrode area, durations of treatment, total energies delivered, are all similar to the respective methods and parameters in the predicate devices.

Conclusions:

Results of performance testing, summarized in this 510k notice, demonstrate that the Venus Viva™ device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices, Venus Viva SR (K150161) and Legacy BX (K142910).

Therefore, based on the same intended use and indications for use, similar technological characteristics and principles of operation, the Venus Viva™ device is substantially equivalent to its predicate devices, Venus Viva SR (K150161) and Legacy BX (K142910).