June 26, 2020

Venus Concept USA Inc.
Dr. Yoni Iger
Vice President Quality Assurance/Regulatory Affairs/Clinical Affairs
1880 N Commerce Pkwy, Suite 2
Weston, Florida 33326

Re: K201164
Trade/Device Name: Venus Viva MD 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 28, 2020
Received: May 1, 2020

Dear Dr. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201164

Device Name

Venus Viva MD™

Indications for Use *(Describe)*

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

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

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 – K201164

Venus Viva MD™

Applicant Name: Venus Concept USA Inc.
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Tel: +1 888 907-0115

Contact Person: Dr. Yoni Iger
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Date Prepared: June 24, 2020

Trade Name: Venus Viva MD™

Classification Name: 21 CFR 878.4400 Electrosurgical cutting and coagulation device and accessories

Product Code: GEI

Classification: Class II Medical Device

Classification Panel: General & Plastic Surgery

Predicate Device: Venus Viva SR Device (K150161)
Venus Legacy BX Device (K142910)

Intended Use/Indication for Use:

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

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

Device Description:

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

The Venus Viva MD™ 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 MD and Diamondpolar applicators can now be connected simultaneously to a single console, the Venus Viva MD™ console.

Additionally, the Viva MD applicator is supplied with single use detachable tips with 80- or 160-electrode pins. The 160-pin tip was previously cleared within Venus Viva SR (K150161).

Technological Characteristics:

The Venus Viva MD™ is a computerized system generating Radiofrequency (RF) energy and Pulsed Magnetic Fields (PMF), which are emitted into the skin. The Venus Viva MD™ device delivers RF energy to the patient's skin with the use of the Viva MD applicator or a combination of RF and PMF energies with the use of the Diamondpolar applicator. The Venus Viva MD™, when operated with the Viva MD applicator, is designed to deliver radiofrequency energy to the skin in a non-homogenous manner, via an array of multi-electrode pins. The array delivers RF energy to the skin, resulting in heating of skin directly below and in contact with the electrodes, to temperatures leading to ablation and resurfacing of the skin. The energy generates heating that ablates within the epidermis, papillary and reticular dermis, triggering slow collagen remodeling.

Each RF electrode and its surrounding PMF coil of the Diamonpolar applicator of the Venus Viva MD™ device simultaneously emits RF and PMF energy. RF-energy induced heat is to cause the dermal collagen to contract, producing an anti- wrinkle effect. The non-ablative heat in the dermal tissue triggers a second delayed effect in which collagen fibers are built, enhancing the anti-wrinkle and anti-rhytides effect. The PMF energy provokes skin tissue for extra collagen production and amplifies the RF induced effect.

Performance Data:

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

Performance – Bench Testing: The Venus Viva MD™ device underwent performance testing, including software validation and device verification tests in order to evaluate the Venus Viva MD™ 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 MD™ device has the same RF and PMF output specifications as those reported for the predicate devices and

therefore, is substantially equivalent to the predicates with respect to device performance.

Performance – Animal Testing: The animal study was conducted to histologically compare average ablation dimensions and healing of ablated zones in porcine skin when treated with an 80-pin tip and 160-pin tip of the Venus Viva MD™ system. Overall, the treated sites in both pin tip groups showed that the skin was ablated and thereafter passed resurfacing and desired healing with complete re-epithelialization of the epidermis and the beginnings of new collagen synthesis.

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

- IEC 60601-1:2012 Ed. 3.1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Ed. 4, General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-2:2017 Ed. 6 Medical electrical equipment - Part 2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
- IEC 60601-1-6: 2013 Ed.3.1, General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62304:2015 Medical device software – Software life cycle processes

Software Testing: The software was also subject 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 related safety or effectiveness concerns.

Substantial Equivalence:

The following table compares the Venus Viva MD™ 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.

Table 1. Venus Concept, Ltd.'s Venus Viva MD™ Substantial Equivalence

	Venus Viva MD™ Venus Concept Ltd.	**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 MD™ Device is a non- invasive device intended to be used by aesthetic-related 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)

	Venus Viva MD™ Venus Concept Ltd.	**Venus Viva SR Venus Concept Ltd. (K150161)**	**Venus Legacy BX Venus Concept Ltd. (K142910)**
Applicator Footprint Dimensions	Viva MD: 1.33 cm^2 (160-pin tip) 1.33 cm^2 (80-pin tip) Diamondpolar: 2.9 cm^2	Viva SR: 1.33 cm^2(160-pin tip)	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 subject Venus Viva MD™ and the predicates Venus Viva SR device (K150161) and Venus Legacy BX device (K142910) share the same intended use and the same underlying technology with similar technological characteristics and principles of operation. The design and components in the Venus Viva MD™ 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 modifications between the Venus Viva SR device and the Venus Viva MD™ device is the integration of the Diamondpolar applicator and an addition of the 80-pin tip in the Venus Viva MD™ device. The Diamondpolar applicator was previously cleared for the additional predicate device Venus Legacy BX (K150161) and the 80-pin tip presenting minor design changes while preserving the same characteristics such as total output energy, active treatment area and materials if compared to the 160-pin tip cleared previously for the primary predicate Venus Viva SR device (K150161).

The combination of two of the predicate applicators into a single device and any differences between the Venus Viva MD™ and its predicates (K150161, K142910) were carefully evaluated and it was concluded that they do not present any new questions of safety or effectiveness.

The safety features and compliance with safety standards of the Venus Viva MD™ 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). Sterilization instructions for the detachable tips of the Viva MD applicator are the same sterilization instructions that were previously validated for the predicate device, the company's Venus Viva SR (K150161).

Furthermore, the Venus Viva MD™ device underwent performance testing, including bench testing, software validation testing, electrical safety according to IEC 60601-1, electromagnetic compatibility testing according to IEC 60601-1-2 and others. These performance tests in addition to a bench test demonstrated that the differences in the technological characteristics between the subject and predicate devices do not raise new types of safety or effectiveness concerns.

Conclusions:

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