September 6, 2019

Venus Concept USA Inc.
% Elissa Burg
Regulatory Consultant
BioVision Ltd
Had Nes 183
Had Nes, Israel 1295000

Re: K191528
Trade/Device Name: Venus Legacy Pro Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI, PBX
Dated: June 6, 2019
Received: June 10, 2019

Dear Elissa Burg:

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

V. INDICATIONS FOR USE STATEMENT

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 below.

510(k) Number *(if known)* K
K191528

Device Name
Venus Legacy Pro

Indications for Use *(Describe)*

When used with the Octipolar (LB1) or Diamondpolar (LF1) applicators, the Venus Legacy Pro device is 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.

When used with the 4D Body (LB2) or 4D Face (LF2) applicators, the Venus Legacy Pro device is intended for the delivery of non-thermal RF combined with Massage and magnetic field pulses for the treatment of the following medical conditions:

- Relief of minor muscles aches and pain, relief of muscle spasm
- Temporary improvement of local blood circulation
- Temporary reduction in the appearance of cellulite

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 - K191528

VENUS LEGACY PRO DEVICE

Applicant Name: Venus Concept USA Inc. 1880
N Commerce Pkwy, Suite 2
Weston, FL33326, USA Tel:
+972 -549599215

Contact Person: Dr. Yoni Iger
VP QA/RA/CA
Venus Concept USA Inc.

Date Prepared: June 6, 2019

Trade Name: Venus Legacy Pro Device

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

Product Codes: GEI, PBX

Classification: Class II Medical Device

Classification Panel: General & Plastic Surgery

Predicate Devices: Venus Legacy BX (K142910)
Venus Legacy CX (K143554)

Intended Use/Indication for Use:

When used with the Octipolar (LB1) or Diamondpolar (LF1) applicators, the Venus Legacy Pro device is 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.

When used with the 4D Body (LB2) or 4D Face (LF2) applicators, the Venus Legacy Pro device is intended for the delivery of non-thermal RF combined with Massage and magnetic field pulses for the treatment of the following medical conditions:

- Relief of minor muscles aches and pain, relief of muscle spasm
- Temporary improvement of local blood circulation
- Temporary reduction in the appearance of cellulite

Device Description:

The Venus Legacy Pro device consists of a console (main unit) and four applicators - Octipolar (LB1), Diamondpolar (LF1), 4D Body (LB2) and 4D Face (LF2). The console contains a power supply unit, an RF generator (power module, on main board), a suction module (vacuum), a controller unit (on main board) and a touchscreen user interface and display panel.

The Venus Legacy Pro device combines two previously cleared devices (Legacy BX, K142910 and Legacy CX, K143554) into one device. The two applicators that were cleared for the Legacy BX Device - Octipolar (LB1) and Diamondpolar (LF1) and the two applicators that were cleared for the Legacy CX device - 4D Body (LB2) and 4D Face (LF2) can now be connected simultaneously to a single console, the Legacy Pro device's console.

Technological Characteristics:

The Venus Legacy Pro device provides RF treatments combined with emitted magnetic fields via the Octipolar (LB1) and Diamondpolar (LF1) applicators and RF treatments combined with emitted magnetic fields and vacuum massaging via the 4D Body (LB2) and 4D Face (LF2) applicators. The RF currents heat the adipose and muscular tissues to trigger tissue level changes leading to temporary reduction in the appearance of cellulite and temporary relief of muscle pain and muscle spasm. The RF heating effect also improves local blood circulation in the dermal and sub dermal layers. The PMF assists in achieving treatment desired effect. The Vacuum is mainly used for the massaging of deep tissues by creating mild to deep suction. The vacuum massage contributes to the dermal, sub-dermal and adipose tissues shrinkage and improves the contact surface and electrical coupling between electrodes and tissue.

Performance Data:

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

- Performance Bench Testing: Several performance tests were performed, including software validation and device verification tests in order to evaluate the Venus Legacy Pro device's outputs per specifications, and as compared to the predicate device's specifications. The results demonstrated that the differences in the technological characteristics of the subject and predicate devices do not raise new types of safety or effectiveness concerns.

  In addition, bench tests were conducted to demonstrate the ability of the LB2 and LF2 applicators operated by the Venus Legacy Pro device, to maintain the appropriate desired treatment temperature of 41ºC-45ºC on the surface of the human skin while using the 4D Body (LB2) applicator, and 39ºC-45ºC using the 4D Face (LF2) applicator

- 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 60601-1:2012 Ed. 3.1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
  - IEC 60601-2-2 :2017 Ed. 6, Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
  - IEC 60601-1-6: 2013 Ed.3, General requirements for basic safety and essential performance - Collateral standard: Usability
  - IEC 60601-1-2:2014 Ed. 4, General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
  - IEC 62304 Medical device software – Software life cycle processes (2006/AMD2015)

- 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.

Substantial Equivalence:

The following table compares the Venus Legacy Pro 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 Legacy Pro Substantial Equivalence

	Venus Legacy Pro **Venus Concept Ltd.** **(K191528)**	**Venus Legacy BX** **Venus Concept Ltd.** **(K142910)**	**Venus Legacy CX** **Venus Concept Ltd.** **(K143554)**
Class, Product Code, Regulation	Class II, GEI & PBX, 21 CFR 878.4400	Class II, GEI, 21 CFR 878.4400	Class II, PBX, 21 CFR 878.4400
Indications for Use	When used with the Octipolar (LB1) or Diamondpolar (LF1) applicators, the Venus Legacy Pro device is 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. When used with the 4D Body (LB2) and 4D Face (LF2) applicators, the Venus Legacy Pro device is intended for the delivery of non-thermal RF combined with Massage and magnetic field pulses for the treatment of the following medical conditions: • Relief of minor muscles aches and pain, relief of muscle spasm • Temporary improvement of local blood circulation • Temporary reduction in the appearance of cellulite	The Venus Legacy BX is a non-invasive 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.	The Venus Legacy CX device is intended for the treatment of the following medical conditions; using the LB2 and LF2 applicators for delivery of non-thermal RF combined with massage and magnetic field pulses: • Relief of minor muscle aches and pain, relief of muscle spasm • Temporary improvement of local blood circulation • Temporary reduction in the appearance of cellulite.

	Venus Legacy Pro **Venus Concept Ltd.** **(K191528)**	**Venus Legacy BX** **Venus Concept Ltd.** **(K142910)**	**Venus Legacy CX** **Venus Concept Ltd.** **(K143554)**
Energy Used / Delivered	1. RF Energy 2. Pulsed Magnetic Field (PMF) 3. Vacuum	1. RF Energy 2. Pulsed Magnetic Field (PMF)	1. RF Energy 2. Pulsed Magnetic Field (PMF) 3. Vacuum
Applicator Footprint Dimensions	LB1: 23.7 cm^2 LF1: 2.9 cm^2 LB2: 38.5 cm^2 LF2: 4.9 cm^2	LB1: 23.7 cm^2 LF1: 2.9 cm^2	LB2: 38.5 cm^2 LF2: 4.9 cm^2
Integral Thermometer	Yes	Yes	Yes
Performance	Frequency: 1MHz Maximal RF output power for each applicator - Octipolar (LB1), Diamondpolar (LF1), 4D Body (LB2) and 4D Face (LF2): up to 150W PMF Power: 15 Gauss (15Hz) Vacuum pressure: -400mbar	Frequency: 1MHz Maximal RF output power for each applicator – Octipolar (LB1) & Diamondpolar (LF1): up to 150W PMF Power: 15 Gauss (15Hz)	Frequency: 1MHz Maximal RF output power: 50W (4D Body (LB2) applicator), 20W (4D Body (LB2) applicator) PMF Power: 15 Gauss (15Hz) Vacuum pressure: -400mbar
Materials	Materials are biocompatible	Materials are biocompatible	Materials are biocompatible
Power requirements	100-120 VAC / 60Hz 220-240 VAC / 50Hz	100-120 VAC / 60Hz 220-240 VAC / 50Hz	100-120 VAC / 60Hz 220-240 VAC / 50Hz

As described in the comparison table above, the Venus Legacy Pro device has the same intended use and a combination of the indications of the predicates previously cleared Venus devices. The device also has very similar technological characteristics compared to the predicate devices. The design and components in the Venus Legacy device, including the console and the applicators are similar to the design and components found in the predicates Legacy BX and Legacy CX devices. The technological differences, including the maximum output power for the 4D Body (LB2) and 4D Face (LF2) applicators and the difference in the applicator's biocompatible raw materials, do not alter the device's core technology or performance and do not raise new questions of safety and effectiveness.

Furthermore, the Venus Legacy Pro device underwent performance testing, including bench testing, Software validation testing, electrical safety according to IEC 60601-1 and electromagnetic compatibility testing according to IEC 60601-1-2. 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:

Based on the same intended use and indications for use, similar technological characteristics and principles of operation, the Venus Legacy Pro device is substantially equivalent to its predicate devices, Legacy BX (K142910) and Legacy CX (K143554).