Venus Concept USA Inc.
℅ Elissa Burg
Regulatory Consultant
BioVision Ltd
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June 25, 2019

Re: K190743
Trade/Device Name: Venus Bliss
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX, PKT
Dated: March 17, 2019
Received: March 22, 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,

Neil R.P. Ogden, MS
Assistant Director, THT4A4
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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number *(if known)* K 190743

Device Name: Venus Bliss

Indications for Use *(Describe)*

The Venus Bliss device is a diode laser system intended for non-invasive lipolysis of the abdomen and flanks in individuals with a Body Mass Index (BMI) of 30 or less.

In addition, the Venus Bliss device is intended for the treatment of the following medical conditions; using the MP^2 applicator for delivery of RF energy 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

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.

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

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Attachment 5

Revised 510(k) Summary

VI. 510(k) SUMMARY

VENUS BLISS 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: March 17, 2019

Trade Name: Venus Bliss device

Classification Name: 21 CFR 878.4400
21 CFR 878.5400

Product Codes: PBX, PKT

Classification: Class II Medical Device

Classification Panel: General & Plastic Surgery

Predicate Devices: Venus Legacy CX (K143554)
Cynosure's SculpSure (K160470)

Intended Use/Indication for Use:

The Venus Bliss device is a diode laser system intended for non-invasive lipolysis of the abdomen and flanks in individuals with a Body Mass Index (BMI) of 30 or less.

In addition, the Venus Bliss device is intended for the treatment of the following medical conditions; using the MP^2 applicator for delivery of RF energy 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

Device Description:

The Venus Bliss device consists of a console (main unit), one RF applicator and four Diode Laser applicators. The system delivers laser (Diode Laser Applicators) and bipolar RF energies, vacuum pressure, and pulsed magnetic fields (PMF) to the skin (MP^2 applicator) and the underlying tissues of the treatment area.

The console of the Venus Bliss device contains a power supply unit, Laser and RF controllers, (power modules, on main board), a suction module (vacuum), a controller unit (on main board), Laser water cooling system (power module, on main board), a touch- screen user interface and display panel.

Technological Characteristics:

Venus Bliss delivers laser energy to the subcutaneous tissue layers via the four diode laser applicators connected to the console. The console utilizes diode laser modules as sources of optical energy and the optical output is fiber-coupled through the applicator to the treatment area. The laser applicators are coupled to the patient's body while using a dedicated belt for the entire treatment. Individual adjustment of the laser output power is provided for each applicator to achieve maximum safety and efficiency for the patient. The laser applicators have an integrated contact skin cooling system to enhance safety and comfort of the treatment.

In addition, the Venus Bliss device (MP^2 applicator) provides RF treatments combined with emitted magnetic fields and vacuum massaging. The Vacuum is mainly used for the massaging of deep tissues by creating mild to deep suction. The vacuum massage improves the contact surface between electrodes and tissue. 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 sub dermal layers. The PMF assists in achieving treatment effect.

Performance Data:

Venus Concept conducted several performance tests to demonstrate that the Venus Bliss 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 Bliss device 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.

- 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 60825-1:2014 Ed.3, Safety of laser products - Part 1: Equipment classification and requirements

    - IEC 60601-2-22:2007 Ed. 3 Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

    - 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 tables compares the Venus Bliss 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.

Substantial Equivalence Table #1 for the RF Applicators:

	Venus Bliss **Venus Concept Ltd.**	**Venus Legacy CX** **Venus Concept Ltd.** **K143554**
Class, Product Code, Regulation	Class II, PBX, 21 CFR 878.4400	Class II, PBX, 21 CFR 878.4400
Indications for Use	The Venus Bliss device is intended for the treatment of the following medical conditions; using the MP^2 applicator for delivery of RF energy 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.	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.
Energy Used / Delivered	1. RF Energy 2. Pulsed Magnetic Field (PMF) 3. Vacuum	1. RF Energy 2. Pulsed Magnetic Field (PMF) 3. Vacuum
Applicator Footprint Dimensions	MP^2: 38.5 cm^2	LB2: 38.5 cm2
Performance	Frequency: 1MHz Vacuum pressure: -400mbar Maximal RF output power: 100W (MP^2 applicator) PMF Power: 15 Gauss (15Hz)	Frequency: 1MHz Vacuum pressure: -400mbar Maximal RF output power: 50W (LB2 applicator) PMF Power: 15 Gauss (15Hz)
Materials	Biocompatible	Biocompatible
Power requirements	100-120 VAC / 60Hz 220-240 VAC / 50Hz	100-120 VAC / 60Hz 220-240 VAC / 50Hz

Substantial Equivalence Table #2 for the Diode Laser Applicators:

	Venus Bliss **Venus Concept Ltd.**	**SculpSure Laser System** **Cynosure Inc.** **K160470**
Class, Product Code, Regulation	Class II, PKT, 21 CFR 878.5400	Class II, PKT, 21 CFR 878.5400
Indications for Use	The Venus Bliss device is a diode laser system intended for non-invasive lipolysis of the abdomen and flanks in individuals with a Body Mass Index (BMI) of 30 or less.	The Cynosure SculpSure is a diode laser system intended for non- invasive lipolysis of the abdomen and flanks in individuals with a Body Mass Index (BMI) of 30 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen and flanks.
Lipolysis Method	Heat-assisted	Heat-assisted
Energy Used / Delivered	Diode Laser	Diode Laser
Components	System Console (with graphical user interface) 4 Applicators - Sapphire light guides - LED contact sensors	System Console (with graphical user interface) 4 Applicators - Sapphire light guides - LED contact sensors
Wavelength	1064 ± 10nm (infrared)	1060 ± 20nm (infrared)
Spot Size	6 x 6 cm^2 on each of the Applicator heads	4 x 6 cm^2 on each of the Applicator heads
Pulse Width (laser ON time)	CW	CW
Power Density	Up to 1.4 W/cm^2	Up to 1.4 W/cm^2
Attachment to patient	Belt	Belt
Electrical Power	100-240V~50/60 Hz, Single Phase	200-240V~50/60 Hz, Single Phase
Cooling system	Yes	Yes
Materials	Biocompatible	Biocompatible

As described in the comparison tables above, the Venus Bliss device has the same intended use and indications for use, similar technological characteristics, and principles of operation as its predicate devices. The technological differences between the Venus Bliss device and its predicate devices do not raise any new issues of safety or effectiveness. The Venus Bliss device and its predicate devices Legacy CX (K143554) and SculpSure (K160470) are based on the same core technology of RF along with PMF and vacuum massaging (as in Legacy CX) and Diode Laser (as in SculpSure), for the same indications for use. The design and components in the Venus Bliss device, including the console and the applicators are similar to the design and components found in the predicates. The technological differences, including the maximum output power for the RF applicator and the spot size of the Laser applicators, do not alter the device's core technology or performance.

Furthermore, the Venus Bliss device underwent performance testing, including software validation testing, electrical safety and electromagnetic compatibility testing. 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 Bliss device is substantially equivalent to its predicate devices, Legacy CX (K143554) and Cynosure's SculpSure (K160470).