DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Venus Concept USA Ltd.
Tal Bresler-Stramer, Ph.D, RAC
Vice President Quality Assurance/Regulatory Affairs
4556 North Hiatus Road
Sunrise, Florida 33351

August 4, 2015

Re: K143554
Trade/Device Name: Venus Legacy CX
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device & Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: July 1, 2015
Received: July 1, 2015

Dear Dr. Bresler-Stramer:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*

K143554

Device Name

Venus Legacy CX

Indications for Use *(Describe)*

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

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)

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.

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510(k) SUMMARY

VENUS LEGACY CX DEVICE

Applicant Name: Venus Concept USA Inc.
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Contact Person: Tal Bresler-Stramer, Ph.D., RAC, VP QA/RA Venus Concept Ltd. Venus Concept Ltd.

Date Prepared: August 4, 2015

Trade Name: Venus Legacy CX device

Classification Name: 21 CFR 878.4400 (electrosurgical cutting and coagulation device and accessories) (Product code PBX)

Classification: Class II Medical Device

Predicate Device: Viora Ltd.'s Reaction System (K090221)

Intended Use/Indication for Use:

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

Device Description:

The Venus Legacy CX device consists of a console (main unit) and two applicators (LB2, LF2). The console in the Venus Legacy CX device 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 touch-screen user interface and display panel. The Venus Legacy CX device 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 contributes to the sub-dermal and adipose tissues shrinkage and 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.

Technological Characteristics:

The Venus Legacy CX Device has similar technological characteristics to the Viora Reaction device, as both use RF energy and mechanical manipulation to achieve the same intended use. The design and components of the Venus Legacy CX device, including the console (with power supply, RF generator, suction module, main CPU and display panel) and the applicators (with cable, connector to console, and vacuum pump) are similar to those of the predicate Viora Reaction device. The differences in the design and configuration of the applicators, as well as the additional PMF energy source in the Venus Legacy CX device, do not influence the core technology to achieve the indicated effects. As demonstrated in the bench tests, the performance specifications (including frequency, RF electrical power, and vacuum power) of the Venus Legacy CX device are substantially equivalent to those of the Viora Reaction device. Patient contact materials are also similar. Furthermore, the Venus Legacy CX device underwent performance testing, including RF output and thermal profile testing, software validation testing, electrical safety testing according to AAMI/ANSI ES 60601-1, and electromagnetic compatibility testing according to IEC 60601-1-2. These performance tests demonstrated that the minor differences in the technological characteristics between the subject and predicate devices do not raise new types of safety or effectiveness concerns.

Performance Data:

Performance testing of the Venus Legacy CX demonstrated that the device performs as intended and is substantially equivalent to its predicate, as listed below.

- Performance Bench Testing: Several performance tests were performed in order to evaluate the Venus Legacy CX device outputs per specifications, and as compared to the Viora Reaction predicate device specifications. The results demonstrated that the Venus Legacy CX device has equivalent RF output specifications as the predicate Viora Reaction device. Performance testing was also conducted to evaluate the thermal profile of the Venus Legacy CX as compared to the Viora Reaction predicate in porcine tissue. The testing demonstrated that the thermal profile of the Legacy CX treatment is very similar to that of the Viora Reaction predicate across multiple assessments, supporting substantially equivalent performance.

- 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.

    - AAMI/ANSI ES60601-1, Medical Electrical Equipment -- Part 1: General Requirements For Basic Safety And Essential Performance

    - IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests

- IEC 60601-2-2, Medical Electrical Equipment - Part 2: Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

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

- Cleaning and Disinfection Testing: A validation study of the cleaning and disinfection instructions for the Legacy CX applicators was conducted, and all results were passing.

- Biocompatibility: The biocompatibility of the device was established based on the prior clearance of the company's Venus Freeze $(MP)^2$ device (K111670), which has the same tissue contacting materials for the same type of patient contact. In addition, the applicator plastic material was demonstrated to be biocompatible in Cytotoxicity testing (ISO 10993-5); Intracutaneous testing (ISO 10993-10); and Guinea Pig Maximization Sensitization testing (ISO 10993-10).

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 Venus Legacy CX Device has the same intended use and similar indications for use, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Venus Legacy CX device and its predicate device do not raise any new issues of safety or effectiveness. The Venus Legacy CX device and the Viora Reaction device are based on the same core technology of RF heating and vacuum massaging for the same indications for use. The design and components in the Venus Legacy CX device, including the console and the applicators are similar to the design and components found in the predicate Viora Reaction device. The minor technological differences, including some differences in device design and the addition of the PMF energy source in the Venus Legacy CX device, do not alter device core technology or performance. The performance of the Venus Legacy CX device is substantially equivalent to that of the Viora Reaction device, as demonstrated in testing.

Conclusions:

Therefore, based on the same intended use and similar indications for use, technological characteristics, and principles of operation, the Venus Legacy CX device is substantially equivalent to the Viora Reaction predicate device.