DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 19, 2014

Venus Concept USA Incorporated
% Ms. Ahava Stein
A. Stein – Regulatory Affairs Consulting LTD
% MEDX Ventures Group LLC
175 Derby Street, Unit 27 Suite 1
Hingham, Massachusetts 02043

Re: K142910
Trade/Device Name: Venus Legacy BX Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 19, 2014
Received: November 24, 2014

Dear Ms. Stein:

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 Industry and Consumer Education 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" (21CFR 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 Industry and Consumer Education 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,

Binita S. Ashar -S

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 below.

510(k) Number *(if known)*
K 142910

Device Name
Venus Legacy BX Device

Indications for Use *(Describe)*
The Venus Legacy BX Device 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

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 BX DEVICE

510(k) Number K142910

Applicant Name:

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Date Prepared: September 30, 2014

Trade Name: Venus Legacy BX Device

Classification Name: CFR Classification section 878.4400; (Product code GEI)

Classification: Class II Medical Device

Predicate Device:

The Venus Legacy BX Device is substantially equivalent to the previously cleared, Venus Freeze $(MP)^2$ device, also manufactured by Venus Concept Ltd.

Device	Manufacturer	510(k) No.
Venus Freeze $(MP)^2$	Venus Concept Ltd.	K111670

Device Description:

The Venus Legacy BX device is a non-invasive, non-ablative medical aesthetic device. It is designed to deliver RF (Radio Frequency, 1MHz) energy and PMF (Pulsed Magnetic Field, 15Hz) energy to the skin. RF energy heats the tissue to trigger cellular changes for the intended use. The RF treatment is supplemented with an adjunct magnetic energy for the reduction of the downtime healing process.

The device consists of an RF Power Module, a Pulsed Magnetic Field (PMF) module, two hand piece applicators, and a console with control electronics and an LCD touch screen.

Device Specifications:

Maximal RF Output Power: 150W
RF Output Frequency: 1[MHz]
Magnetic Frequency: Pulse, 15Hz
Maximal Magnetic Field: 15 Gauss
Dimension: 40cm W x 40cm D x 100cm H (15.7'' W x 15.7'' D x 39.4'' H)
Weight: 40 Kg (88 lbs)
Main Line Frequency (nominal): 50-60 Hz
Input Voltage (nominal): 100-240 VAC

Intended Use/Indication for Use:

The Venus Legacy BX device 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.

Performance Standards:

The Venus Legacy BX device has been tested and complies with the following voluntary recognized standards:

- IEC 60601-1, (Third Edition, 2005 / 2006), Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2, (Third Edition, 2007), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests
- IEC 60601-2-2 (Fifth Edition, 2009): Medical Electrical Equipment - Part 2: Particular requirements for the safety of high frequency surgical equipment.

Non-Clinical (Bench) Performance Data:

A bench test was performed to measure the RF output parameters; PMF output parameters and temperature stability in the Venus Legacy BX device and compare them to the RF output measurements, PMF output parameters and temperature stability in the Venus Freeze $(MP)^2$ device. The results of the bench test demonstrated that the Venus

Legacy BX 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.

Pre-Clinical (Animal Study) Performance Data:
Not Applicable

Clinical Performance Data:
Not Applicable

Substantial Equivalence:
The indications for use and technological characteristics of the Venus Legacy BX device are substantially equivalent to the indications for use and technological characteristics of the Venus Freeze $(MP)^2$ device.

The Venus Legacy BX device is a modified device of the Venus Freeze $(MP)^2$ device, previously cleared under 510k No. K111670. The modifications are exclusively design related with a new outer design yet with the same technology and components as in the Venus Freeze $(MP)^2$ device.
The inner design and components in the Venus Legacy BX device, including the console (with power supply, RF generator, controller and display panel) and the hand piece applicators (with cable, connector to console) are similar to the design and components found in the Venus Freeze $(MP)^2$ device. The safety features and compliance with safety standards in the Venus Legacy BX device are similar to the safety features and compliance with safety standards found in the predicate devices (provided in Section 7). The patient contact materials are biocompatible in compliance with ISO10993 Standard and similar to materials found in the Venus Freeze $(MP)^2$ device. The Venus Legacy BX device underwent performance testing, including software validation testing (provided in Section 12) and electrical and mechanical safety testing according to IEC 60601-1 and electromagnetic compatibility testing according to IEC 60601-1-2 (provided in Section 12). The performance specifications (including RF electrical power output, PMF output and temperature stability) of the Venus Legacy BX device are substantially equivalent to those in the Venus Freeze $(MP)^2$ device, as shown in the performance bench tests provided in section 12. The results of the tests demonstrate that the specifications are similar to those of the predicate device. These performance tests demonstrate that the device specifications meet the system requirements and that the minor differences in design do not raise new safety or effectiveness concerns.

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 device.

Consequently, it can be concluded that the Venus Legacy BX device is substantially equivalent to the predicate Venus Freeze $(MP)^2$ device, cleared under 510(k) K111670; and therefore, may be legally marketed in the USA.

Conclusions:
Based on the performance testing and comparison to predicate devices, the Venus Legacy BX device is substantially equivalent to the Venus Freeze $(MP)^2$ predicate device for the mentioned intended use.