October 14, 2021

Venus Concept USA Inc.
Yoni Iger
VP Regulatory, Science & Technology
1880 N Commerce Pkwy, Suite 2
Weston, Florida 33326

Re: K211461
Trade/Device Name: Family of Venus RF Systems - Venus Freedom
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: August 10, 2021
Received: August 17, 2021

Dear Yoni 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)* K211461

Device Name

Family of RF Systems - Venus Freedom

Indications for Use *(Describe)*

The Venus Freedom device is intended for the treatment of the following medical conditions; using the Pearl, Diamond and Slim 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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VI. 510(k) SUMMARY

VENUS FREEDOM DEVICE – K211461

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

Contact Person: Dr. Yoni Iger
VP Regulatory, Science & Technology
Venus Concept USA Inc.
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Tel: +1 888 907-0115

Date Prepared: October 13, 2021

Trade Name: Venus Freedom Device

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

Product Code: PBX

Classification: Class II Medical Device

Classification Panel: General & Plastic Surgery Panel

Predicate Device: Venus Heal device (K182094)

Intended Use/Indication for Use:
The Venus Freedom device is intended for the treatment of the following medical conditions; using the Pearl, Diamond and Slim 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 Freedom device, part of the Family of Venus RF devices, is a noninvasive, non-ablative device that delivers Radiofrequency (RF) energy, along with the Pulsed Electro-Magnetic Field (PEMF), into the skin to generate heat through electrical impedance in the epidermis, dermis, subcutaneous layers, and muscular tissue.

The device consists of a console (main unit) and three applicators (Pearl, Diamond and Slim).

The Venus Freedom RF energy, PEMF and tissue manipulation (massage), are utilized to trigger changes in the tissue which result in local blood circulation improvement, muscle spasm relief along with pain relief. Temporary reduction in the appearance of cellulite is similarly achieved by the combination of these three main mechanisms: tissue manipulation (massage), RF delivery and PEMF delivery.

Consistent with the previous clearance, the device is intended to be used in professional healthcare facilities (prescription use) just as the predicate.

Comparison of Technological Characteristics:

The following table compares the subject Venus Freedom device to its predicate device with respect to intended use, technological characteristics and principles of operation, providing detailed information regarding the basis for the determination of substantial equivalence.

Parameter	**Proposed Device:** **Venus Freedom** **Venus Concept Inc.**	**Predicate Device:** **Venus Heal** **Venus Concept Inc.** **(K182094)**	**Substantial Equivalence**
Product Class, Code	Class II, PBX	Class II, PBX	Same
Indications for Use	The Venus Freedom device is intended for the treatment of the following medical conditions; using the Pearl, Diamond and Slim 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.	The Venus Heal device is intended for the treatment of the following medical conditions; using the Large and Small 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.	Same

Parameter	Proposed Device: Venus Freedom Venus Concept Inc.	Predicate Device: Venus Heal Venus Concept Inc. (K182094)	Substantial Equivalence
Energy Used/ Delivered	RF Energy Pulsed Electro-Magnetic Field (PEMF)	RF Energy Pulsed Electro-Magnetic Field (PEMF)	Same
Tissue Manipulation Mechanism	Massage mechanism	Massage mechanism	Same
Design	Use of RF and PEMF combined energies delivered through applicator and massage of the skin.	Use of RF and PEMF combined energies delivered through applicator and massage of the skin.	Same
Components	Console, including: - Power supply - RF generator - Main CPU - Display panel - PEMF generator Applicators: - Pearl - Diamond - Slim Footswitch	Console, including: - Power supply - RF generator - Main CPU - Display panel - PEMF generator Applicators: - Large - Small	Same New Applicator Addition of Footswitch
Applicators	<u>Pearl Applicator</u>: 6 electrodes 1 PEMF coil <u>Diamond Applicator:</u> 4 electrodes 1 PEMF coil <u>Slim Applicator</u>: 6 electrodes 1 PEMF coil	<u>Large Applicator</u>: 8 electrodes 8 PEMF coils <u>Small Applicator</u>: 4 electrodes 4 PEMF coils	Same delivery of Bipolar RF and PEMF, although different number of electrodes and coils New Applicator
Applicator's disposable tip	Single use disposable per applicator: - Pearl disposable tip - Diamond disposable tip - Slim disposable tip	None, all applicators are reusable	Different

Parameter	Proposed Device: Venus Freedom Venus Concept Inc.	Predicate Device: Venus Heal Venus Concept Inc. (K182094)	Substantial Equivalence
Device Dimensions	16.5x16.5x10.4 in (W × D × H) 42x42x26.5 cm (W × D × H)	16.5x16.5x10.4 in (W × D × H) 42x42x26.5 cm (W × D × H)	Same
Performance	Frequency: 1MHz Max. RF output power: 80W (Pearl, Diamond and Slim applicators) PEMF Power: 15 Gauss (15Hz)	Frequency: 1MHz Max. RF output power: 100W (Large and Small applicators) PEMF Power: 15 Gauss (15Hz)	Same Different Same
Power density per effective treatment area (Watt/cm^2)	Pearl Applicator: 3.75W/cm^2 Diamond Applicator: 24.24W/cm^2 Slim Applicator: 4.5W/cm^2 (1 pair of electrodes)	Large Applicator: 2.6W/cm^2 Small Applicator: 20.4 W/cm^2	Different Different
Materials	Biocompatible materials per ISO 10993-1	Biocompatible materials per ISO 10993-1	Same

Performance Data:

Venus Concept conducted several performance tests to demonstrate that the subject Venus Freedom device complies with performance standards and that it functions as intended per its design.

- Verification test demonstrating that the Venus Freedom device meets the system's technical specification for the max RF power output and max PEMF power density.

- A Bench test which demonstrated the ability of the subject device to maintain a safe treatment temperature on the surface of the human skin with the same protocol that was used for the predicate device, Venus Heal (K182094).

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

- IEC 60601-1: (2005) and A1:2012, Medical Electrical Equipment - Part 1-1: General requirements for basic safety and essential performance

- IEC 60601-1-6: (2010/AMD2013), Medical Electrical Equipment - Part 1-6, General requirements for basic safety and essential performance

- IEC 60601-2-2:2017, Medical Electrical Equipment - Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

- IEC 60601-1-2: 2014, Medical Electrical Equipment, Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

- IEC 62304: (2006/AMD2015) Medical device software – Software life cycle processes

Software Testing:
Software verification and validation testing has been performed; the device functioned as intended and the results observed were as expected.

Biocompatibility:
Biocompatibility testing was performed on the Venus Freedom's disposable tip's materials according to the FDA Guidance and ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process. Testing included cytotoxicity, sensitization and irritation according to standards set forth in ISO 10993- 5, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity and ISO 10993-10 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization. All testing passed.

Conclusions:

The Venus Freedom device is as safe and effective as its predicate device, Venus Heal, cleared under K182094 for the same requested intended use. The Venus Freedom device has the same intended use and indications for use, similar technological characteristics, and the same principle of operation as its predicate device. Performance data demonstrated that the technological differences in the Venus Freedom do not raise any issues of safety or effectiveness in comparison to the predicate device. Thus, the Venus Freedom device is substantially equivalent to its predicate, Venus Heal (K182094) for the requested intended use.