June 9, 2020

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

Re: K200786
Trade/Device Name: Venus Epileve
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: March 19, 2020
Received: March 26, 2020

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,

Colin Kejing Chen
Acting 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)*
K200786

Device Name

Venus Epileve

Indications for Use *(Describe)*

The Venus Epileve is intended for all Fitzpatrick skin types, including tanned skin, for use in dermatology, general and plastic surgery applications for:

- Hair removal;
- Permanent hair reduction (defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen); and
- Treatment of pseudofolliculitis barbae.

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

VENUS EPILEVE

510(k) number K200786

Applicant Name: Venus Concept USA Inc.
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Ste 2, Weston, FL33326, USA
Tel: +972-549599215

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

Date Prepared: June 3, 2020

Trade Name: Venus Epileve

Classification Name: 21 CFR 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology

Product Code: GEX

Classification: Class II Medical Device

Classification Panel: General & Plastic Surgery

Predicate Device: Venus Concept's Velocity Diode Laser System (K162765)

Intended Use/Indication for Use:

The Venus Epileve is intended for all Fitzpatrick skin types, including tanned skin, for use in dermatology, general and plastic surgery applications for:

- Hair removal;
- Permanent hair reduction (defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen); and
- Treatment of pseudofolliculitis barbae

Device Description:

The Venus Epileve device consists of a tabletop console (main unit) and one detachable diode laser applicator. The system console is the main enclosure that holds and contains all external and internal system components: a power supply unit, laser diode driver, controller unit, and touch screen with LCD display. The console incorporates a water cooling system with a pump in order to constantly keep the tip of the applicator, light guide, chilled.

The detachable diode laser applicator is connected to the system via a cable passed through the applicator connectors located in the designated compartment on the system's rear side. When not in use, the applicator can be secured within the applicator cradle on the top panel of the console. The applicator delivers the laser energy to a patient's skin through the applicator's tip made of a sapphire light guide framed in aluminum anodized shells. The applicator is supplied with only one spot size light guide.

The device also comes with a footswitch, goggles, patient eye protectors, and water filling kit.

Technological Characteristics:

The Venus Epileve delivers laser energy to the patient's skin via the diode laser applicator connected to the console. The console utilizes diode laser module as sources of optical energy and the optical output is fiber-coupled through the applicator to the treatment area.

Pulsed laser energy emitted by the system is absorbed by melanin in the hair follicles, which have greater optical absorption at the selected laser wavelength than the surrounding tissue. The selective absorption leads to localized heating and thermal denaturation of the target with minimal effect on the surrounding tissues.

The short- and long-term impact of the selective photo thermolysis on hair subparts caused by diode laser energy emitted into the skin leads to hair removal and permanent hair reduction. The laser applicator has an integrated contact skin cooling system to enhance safety and comfort during the treatment.

The device incorporates several safety features, including an emergency laser stop button, user login and password protection, and other software and hardware settings to mitigate the risk of improper energy release and ensure that system outputs are within specifications.

Performance Data:

Venus Concept conducted several performance tests to demonstrate that the Venus Epileve system 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 Epileve system'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 device do not raise new types of safety or effectiveness concerns.

- Electrical Safety and Electromagnetic Compatibility: In addition, the system 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 60601-1-2:2014 Ed. 4, General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

  - IEC 60601-1-6: 2013 Ed.3.1, General requirements for basic safety and essential performance - Collateral standard: Usability

  - 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 62304:2015 Medical device software – Software life cycle processes

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

These performance tests demonstrated that the device meets the system requirements and do not raise new types of safety or effectiveness concerns. In addition, the patient-contacting materials are biocompatible per ISO 10993.

Substantial Equivalence:

The following table compares the Venus Epileve system 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.

Venus Concept Ltd.'s Venus Epileve Substantial Equivalence Chart

Table 1. Technical Specifications

Parameter	Venus Epileve Venus Concept Ltd. (Subject Device)	Venus Velocity Venus Concept Ltd. (Predicate Device)
510(k) Number	Pending	K162765
Product Class, Code	Class II, GEX	Class II, GEX
Regulation Number	21 C.F.R. § 878.4810	21 C.F.R. § 878.4810
Regulation	Laser surgical instrument for use in general and plastic surgery and in dermatology (878.4810)	Laser surgical instrument for use in general and plastic surgery and in dermatology (878.4810)
Manufacturer	Venus Concept Ltd	Venus Concept Ltd
Intended Use and Indications for Use	The Venus Epileve is intended for all Fitzpatrick skin types, including tanned skin, for use in dermatology, general and plastic surgery applications for: • Hair removal; • Permanent hair reduction (defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen); and • Treatment of pseudofolliculitis barbae.	The Venus Concept Velocity Diode laser is intended for all Fitzpatrick skin types, including tanned skin, for use in dermatology, general and plastic surgery applications for: • Hair removal; • Permanent hair reduction (defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen); and • Treatment of pseudofolliculitis barbae.
Laser System – Technical Specifications		
Main Components	• A tabletop laser console (with graphical user interface) • An applicator with a sapphire light guide	• Floor standing laser console (with graphical user interface). • An applicator with three sizes of sapphire light guides (small, medium, large)
Energy Type	Diode laser	Diode laser
Wavelength	800±15 nm nominal infrared (785-815 nm)	800±15 nm nominal infrared (785-815 nm)
Spot Size	2.0 cm^2 (16.5mm x 12 mm)	• Small: 1.69 cm^2 (13mm x13mm) • Medium: 3.5 cm^2 (13mm x27mm) • Large: 7.0 cm^2 (20mm x 35mm)
Pulse Energy [J]	80 J	• Small: 10-170 J • Medium: 14-140 J • Large: 28-140 J

Energy Density, Fluence [J/cm^2]	4-40 J/cm^2	• Small: 6-100 J/cm^2 • Medium: 6-40 J/cm^2 • Large: 4-20 J/ cm^2
Pulse Duration [msec]	5-170 ms	5 – 170 ms
Frequency [Hz]	Slide Mode: ≤10 Hz , Pulse Mode:≤ 3 Hz	• Small: Slide Mode: ≤10 Hz , Pulse Mode:≤ 3 Hz • Medium: Slide Mode: ≤10 Hz , Pulse Mode:≤ 3 Hz • Large: Slide Mode: ≤ 2 Hz , Pulse Mode:≤ 4 Hz
Max Peak Power [Watt]	1600 W	2400 W
Light guide	Sapphire	Sapphire
Cooling system	Water cooling, closed system Light Guide cooled by TEC	Water cooling, closed system Light Guide cooled by TEC
Light guide cooling	(+5) °C – (+15)°C	(+5) °C – (+15)°C
Beam Delivery	Diode array laser located in applicator/ cooled sapphire contact tip (reusable)	Diode array laser located in applicators/ cooled sapphire contact tip (reusable)
Beam Control	Applicator trigger button or footswitch (optional)	Applicators trigger button
Electrical Requirements	• Voltage: 100-240 VAC • Frequency: 50-60 Hz • Power: ≤0.6 KVA	• Voltage: 100-240 VAC • Frequency: 50-60 Hz • Power: ≤1.2 KVA
Overall Weight	~25 kg (55 lbs)	~35 kg (77.2 lbs)
System console Dimensions	45 x 56 x 35 cm (W x D x H, not packed)	65 x 55 x 110 cm (W x D x H, not packed)
Display	LCD touch display 15 inch	LCD touch display 10.4 inch

As described in the comparison table above, the subject Venus Epileve and the predicate Venus Velocity (K162765) devices share the same intended use and same indications for use, and similar technological characteristics and principles of operation. The differences in the system console design, and available energy parameters between the Venus Epileve and its predicate (K162765) do not present any new questions of safety or effectiveness, as is further supported by the wide range of diode lasers already cleared for the same indications.

Furthermore, the Venus Epileve device underwent performance testing, including bench testing, software validation testing, electrical safety according to IEC 60601-1, electromagnetic compatibility testing according to IEC 60601-1-2, laser safety testing according to IEC 60825-1 and others. 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 Epileve device is substantially equivalent to its predicate device Venus Velocity (K162765).