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

January 11, 2017

Venus Concept Ltd.
% Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1835 Market St., 29th Floor
Philadelphia, Pennsylvania 19103

Re: K162765
Trade/Device Name: Venus Velocity
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: November 29, 2016
Received: November 29, 2016

Dear Ms. Hogan:

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" (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 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,

Jennifer R. Stevenson -A

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)*

K162765

Device Name

Venus Velocity

Indications for Use *(Describe)*

The Venus Velocity 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.

510(k) SUMMARY

Venus Concept Ltd.'s Venus Velocity

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Venus Concept Ltd.
4556 N. Hiatus Road
Sunrise, FL 33351

Phone: 416.907.0115
Facsimile: 954.572.5680

Contact Person: Tal Bresler-Stramer, Ph.D., RAC, Vice President, QA/RA

Date Prepared: November 29, 2016

Name of Device and Classification/Product Code

Trade/Proprietary Name: Venus Velocity

Common or Usual Name: Diode laser system

Classification Name: 21 C.F.R. § 878.4810, Laser surgical instrument for use in general and plastic surgery and in dermatology

Product Code: GEX

Predicate and Reference Devices

Predicate Devices: Palomar Medical Technologies, Inc.'s Palomar Vectus Laser (K120622); Lumenis Ltd. LightSheer® Desire (K151947)

Reference Devices: Alma Lasers Modified Diode Laser Module with SHR Treatment Mode for use with the Family of Soprano XL Multi-Application Platforms (K112031); Sandstone Medical's Cheveux Diode Laser System (K100893); Milesman's Milesman Premium (K073300); ILOODA Company's Vikini (K151232); Beijing Anchorfree Technology's Diode Laser Hair Removal System (K141973).

Intended Use / Indications for Use

The Venus Velocity 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.

Technological Characteristics

The Venus Velocity consists of a console, a detachable diode laser applicator, and three interchangeable sapphire light guides/tips (small, medium, and large sizes). A water system and

pump in the console distribute water to cool the handpiece and tips during device use, decreasing the likelihood of burns, discomfort, or pain during treatment. The system is also provided with a water filling kit.

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. The device also comes with goggles and patient eye protectors.

Performance Data

Performance testing of the subject device supports its safety and effectiveness profile for the proposed indications. Electromagnetic compatibility and electrical safety testing was conducted per IEC 60601-1, IEC 60601-1-2, IEC 60601-2-22, and IEC 60825-1. All results were passing. In addition, the patient-contacting materials are biocompatible per ISO 10993-1 and ISO 10993-5. The Venus Velocity also underwent software verification and validation, with results demonstrating that the software is appropriate for release. System verification testing further confirmed that the system performs as intended, and that the energy outputs of the device meet specifications.

Substantial Equivalence

The Venus Velocity has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices, the Palomar Vectus and Lumenis LightSheer Desire laser systems. The minor technological differences between the Venus Velocity and its predicates raise no new issues of safety or effectiveness. The key energy parameters are very similar for the devices, where the available wavelength, spot sizes, pulse durations, fluence outputs, and peak power for the Venus Velocity are within the ranges previously cleared for the predicates. In addition, the higher frequency available with the Venus Velocity does not raise different questions of safety or effectiveness because other laser-based devices for similar indications have also been cleared with the same 10 Hz maximum frequency. Performance data demonstrate that the Venus Velocity performs as intended, and further support that the device performs as intended. Thus, the Venus Velocity is substantially equivalent to its predicates.

Conclusions

The tests outlined above demonstrate that the device performs as intended. The Venus Velocity has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. Minor differences between the subject and predicate devices do not present any new or different types of safety or effectiveness questions. In sum, the Venus Velocity is substantially equivalent to its predicate devices.