



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 20, 2016

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

Re: K152790

Trade/Device Name: Venus Versa System
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: ONF
Dated: December 21, 2015
Received: December 21, 2015

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 yours,

Jennifer R. Stevenson -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

Indications for Use

510(k) Number (if known)

K152790

Device Name

Venus Versa System

Indications for Use (Describe)

The Venus Versa System is a multi-application device intended to be used in aesthetic and cosmetic procedures.

The SR515 and SR580 IPL applicators are indicated for the following:

- Treatment of benign pigmented epidermal and cutaneous lesions including: hyperpigmentation, melasma, ephelides (freckles), lentigines, nevi, and cafe-au-lait macules.
- Treatment of benign cutaneous vascular lesions including: port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, angiomas and spider angiomas, poikiloderma of civatte, leg veins and venous malformations. The HR650 and HR690 IPL applicators are indicated for the removal of unwanted hair and to effect stable long-term or permanent hair reduction for skin types I-IV. Permanent hair reduction is 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.

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 Concept's Venus Versa System

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

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VP QA/RA
Venus Concept, Ltd.

Date Prepared: December 21, 2015

Trade Name of Device

Venus Versa System

Classification Regulation, Name, Product Code

Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810), Product Code: ONF

Predicate and Reference Devices

Predicate Devices: Danish Dermatologic Development A/S's Ellipse I²PL System (K060516) (Primary Predicate), MATTIOLI Pulse TWO/THREE Plus Family (K100053)

Reference Devices: Alma Laser's Harmony Lite Multi-Application Platform (K141237); Emvera Diolux (K123257); Lumenis Inc.'s LightSheer Duet Laser System (K053628); Venus Legacy CX (K143554); Palomar Medical Products, Inc.'s StarLux Pulsed Light System (K041086); Beijing KES Biology Technology's IPL System (K122995); BTL Industries, Inc.'s Exilite (K150051); Beijing Syntech Laser Co.'s APOLLO V+ (K113018); Syneron's ePlus Treatment System (K113868); Cynosure's Icon (K142376); Lynton Lumina (K063427)

Intended Use / Indications for Use

The Venus Versa System is a multi-application device intended to be used in aesthetic and cosmetic procedures.

The SR515 and SR580 IPL applicators are indicated for the following:

- Treatment of benign pigmented epidermal and cutaneous lesions, including: hyperpigmentation, melasma, ephelides (freckles), lentigines, nevi, and cafe-au-lait macules.
- Treatment of benign cutaneous vascular lesions, including: port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, angiomas and spider angiomas, poikiloderma of civatte, leg veins and venous malformations.

The HR650 and HR690 IPL applicators are indicated for the removal of unwanted hair and to effect stable long-term or permanent hair reduction for skin types I-IV. Permanent hair reduction is 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.

Device Description

The Venus Versa System is comprised of a console (controller/CPU) and applicators that deliver Intense Pulsed Light (IPL) optical energy to the treatment area. Four IPL handpieces (SR515, SR580, HR650, HR690) are included with the device system. The Versa device provides individual adjustment of light fluency and pulse duration, and has integrated skin cooling features. Using the IPL applicators, the light energy delivered to the patient's skin is used to treat various conditions via the mechanism of selective photothermolysis.

Technological Characteristics

The Venus Versa System has similar technological characteristics to its predicates. All three devices are IPL systems regulated under 21 CFR 878.4810 as class II devices. The Versa is a multi-application system that allows delivery of IPL energy, similar to its predicates. The Versa and the predicate devices are each designed as a system console with a user interface and applicator(s) indicated for the desired treatment effects. The technological characteristics of the Venus Versa as a system and when used for each of the three proposed indications (vascular lesions, pigmented lesions, hair removal/reduction) are similar to the corresponding parameters of the predicate devices. The technological differences between the Venus Versa and its predicates are minor, including some differences in terms of the spot size, frequency, and pulse duration. However, the key parameters of the Versa affecting treatment outcomes (i.e., IPL wavelengths, fluence levels) are the same or encompassed within the range of the predicate devices. In addition, each of the systems utilizes a light guide and cooling system in delivering treatment. See Table 1 below.

Table 1: Venus Versa System Substantial Equivalence Comparison

Medical Device	Venus Concept Ltd.'s Venus Versa System (K152790)	Danish Dermatologic Development A/S Ellipse I²PL System (K060516)	Mattioli Pulse TWO/THREE Plus Family (K100053)
Class, Product Code, Regulation	Class II, ONF, 21 CFR 878.4810	Class II, GEX, 21 CFR 878.4810	Class II, ONF, 21 CFR 878.4810
Indications for Use	The Venus Versa System is a multi-application device intended to be used in aesthetic and cosmetic procedures. The SR515 and SR580 IPL applicators are indicated for the following: · Treatment of benign pigmented epidermal and cutaneous lesions including: hyperpigmentation, melasma, ephelides (freckles), lentigines, nevi, and cafe-au-lait macules. · Treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, angiomas and spider angiomas, poikiloderma of civatte, leg veins and venous malformations. The HR650 and HR690 IPL applicators are indicated for the removal of unwanted hair and to effect stable long-term or permanent hair reduction for skin types I-IV. Permanent hair reduction is 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.	Ellipse I²PL System is intended for use in dermatology: * Hair removal (permanent hair reduction). * Treatment of benign pigmented lesions (including, but not limited to solar lentigines, ephelides, mottled pigmentation) and benign vascular lesions (including but not limited to diffuse redness, telangiectasias, port wine stains). * Treatment of inflammatory acne. <i>[Table included in indications for use form not included here.]</i>	The MATTIOLI PULSE TWO/THREE PLUS is an Intense Pulse Light (IPL) device family indicated for use in aesthetic applications (based on selective photothermolysis), in the treatment of various benign pigmented lesions and hair removal and that produce different effects depending on the applicator that is used: SA APPLICATOR: Model SN: Wavelengths from 560 - 1200 nm are indicated for treatment of benign pigmented (epidermal and cutaneous) lesions, including hyperpigmentation, warts, lentigines, nevi, melasma, and cafe-au-lait. VA APPLICATOR Model VN: Wavelengths from 510 - 1200 nm are indicated for the treatment of benign vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of civatte; leg veins, facial veins and venous malformations. HR APPLICATORS indicated for the treatment of unwanted hair (i.e. hair removal). Model HN: Wavelengths from 650-1200 nm for skin types I-IV; Model HF: Wavelengths from 710 - 1200

Medical Device	Venus Concept Ltd.'s Venus Versa System (K152790)	Danish Dermatologic Development A/S Ellipse I ² PL System (K060516)	Mattioli Pulse TWO/THREE Plus Family (K100053)
			nm for skin type V The equipment should only be used under medical supervision.
Energy Type	IPL	IPL	IPL
IPL Spectrum	515-950 nm - Lesions: 515-950 nm (SR515); 580-950 nm (SR580) - Pigmented Lesions: 515-950 nm (SR515); 580-950 nm (SR580) - Vascular Lesions: 515-950 nm (SR515); 580-950 nm (SR580) - Hair Removal: 650-950 nm (HR650); 690-950 nm (HR690)	400-950 - Lesions: - Pigmented Lesions: 400-720 nm (PL) - Vascular Lesions: 555-950 nm (VL); 530-750 nm (PR) - Hair Removal: 600-950nm (HR, HR-S); 645-950 nm (HR-D)	510-1200 nm - Lesions: 560-1200 nm (SA); 510-1200 nm (VA) - Hair Removal: 650-1200 nm (HN); 710-1200 nm (HF)
Frequency	Up to 3 Hz	1.5-2.0 s charge time/repetition rate	Up to 1 Hz
Spot Size	10 x 30 mm	10 x 48 mm	10 x 40 mm 15 x 50 mm
Pulse Duration	Up to 50 ms - Lesions (SR515, SR580): 5-20 ms - Pigmented Lesions: 10-20 ms - Vascular Lesions: 10-20 ms - Hair Removal (HR650, HR690): 20-50 ms	1.5-100 ms	14-35 ms
Energy Density (Fluence)	Up to 25 J/cm ² - Lesions: - Pigmented Lesions: 5-20 J/cm² - Vascular Lesions: 6-22 J/cm² - Hair Removal: 6-20 J/cm²	Up to 26 J/cm ² - Lesions: - Pigmented Lesions: up to 18 J/cm² - Vascular Lesions: up to 26 J/cm² - Hair Removal: up to 21 J/cm²	Up to 30 J/cm ² - Skin Rejuvenation (SR): 6-30 J/cm² - Hair Removal (HR): 6-25 J/cm²
Components	System console (with user interface) Applicators Ultrasonic gel	System console (with user interface) Applicators Optical coupling gel	System console (with user interface) Applicators
Light guide	Sapphire light guide	Light guide	Crystal Light Guide
Cooling system	Cooling system	Cooling system (circulating water)	Cooling system (water cooling)

Therefore, the dimensional differences and other minor technological differences between the Versa and its predicates do not present any new or different issues of safety or effectiveness. Therefore, the Venus Versa System presents similar technological characteristics as its predicates, in support of substantial equivalence.

Performance Data and Standards

The performance of the Venus Versa has been demonstrated in testing. Electromagnetic Compatibility and Electrical Safety testing was conducted per AAMI/ANSI ES60601-1, IEC 60601-1-2, and IEC 60601-2-57. All results were passing. In addition, the patient contacting materials are biocompatible per ISO 10993-5. Cleaning and disinfection validation testing has also been completed.

The Venus Versa System also underwent software validation and verification, and results demonstrate that the software was appropriate for release. Bench testing further confirmed that the energy outputs of the Versa met specifications.

Substantial Equivalence

The Venus Versa has the same intended use and similar indications for use, technological characteristics and principles of operation as its predicate devices. The minor technological differences between the Venus Versa and its predicate devices do not raise any new or different issues of safety or effectiveness, given that the key energy parameters are the same or similar for the devices.

Conclusions

The tests outlined above demonstrate that the device performs as intended for the indicated uses of each applicator. Minor differences between the subject and predicate devices do not present any new or different types of safety or effectiveness questions, as confirmed by device performance evaluations. In sum, the Venus Versa System is substantially equivalent to its predicate devices.