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

March 21, 2016

Venus Concept Ltd.
% Janice Hogan
Regulatory Counsel
Hogan Lovells Us Llp
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K153717
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, GEX
Dated: December 24, 2015
Received: December 24, 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 -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 below.

510(k) Number *(if known)*
K153717

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, HR690, HR650XL, and HR690XL 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.

The Venus Concept ACDUAL applicator is intended to be used for the treatment of acne vulgaris.

The Diamondpolar and Octipolar applicators are non-invasive devices intended for use in dermatologic and general surgery procedures for females for the non-invasive treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin types I-IV.
The Viva applicator is intended for dermatological procedures requiring ablation and resurfacing of the skin.

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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Contact Person:
Tal Bresler-Stramer, Ph.D., RAC
VP QA/RA
Venus Concept, Ltd.

Date Prepared: March 18, 2016

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 Codes: ONF, GEX

Predicate/Reference Devices

Predicate Devices:

- Danish Dermatologic Development A/S's Ellipse I^2PL System (K060516)
- MATTIOLI Pulse TWO/THREE Plus Family (K100053)
- Global Medical Technology S.L.'s Platinum GMT IPL System Cloud (K140668)
- Venus Concept Ltd.'s Venus Legacy BX Device (K142910)
- Venus Concept Ltd.'s Viva SR Device (K150161)

Reference Devices:

- Lumenis M22 System (K142860); Alma Laser's Harmony Lite Multi-Application Platform (K141237, K072564); Emvera Diolux (K123257); Lumenis Inc.'s LightSheer Duet Laser System (K053628); BTL's Exilite IPL system (K150051); Beijing KES Biology Technology's IPL System (K122995); Palomar Medical Products, Inc.'s StarLux Pulsed Light System (K041086); Beijing Syntech Laser Co.'s APOLLO V+ (K113018)

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, HR690, HR650XL, and HR690XL 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.

The Venus Concept ACDUAL applicator is intended to be used for the treatment of acne vulgaris.

The Diamondpolar and Octipolar applicators are non-invasive devices intended for use in dermatologic and general surgery procedures for females for the non-invasive treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin types I-IV.

The Viva applicator is intended for dermatological procedures requiring ablation and resurfacing of the skin.

Device Description

The Venus Versa System is comprised of a console (controller/CPU) and ten detachable handpieces (applicators). The system can deliver three types of energies to the patient's skin using the associated applicators:

- Intense Pulsed Light (IPL);
- Radiofrequency (RF);
- Magnetic Pulse (MP^2).

The following ten handpieces are included with the device system: SR515, SR580, HR650, HR690, HR650XL, HR690XL, ACDUAL, Diamondpolar, Octipolar, and Viva.

Technological Characteristics

The Venus Versa System has similar technological characteristics to its predicates. The Versa is a multi-application system that allows delivery of 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 proposed indications (vascular lesions, pigmented lesions, hair removal/reduction, acne) are similar to the corresponding parameters of the predicate devices. The technological differences between the Venus Versa and its predicates are minor, including some minor differences in terms of the spot size, frequency, and pulse duration. However, the key parameters of the Versa affecting treatment outcomes (i.e., wavelengths, fluence levels, total energy) are the same or encompassed within the range of the predicate devices. Therefore, the dimensional differences or other technical 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. See Table 1 below.

Table 1. Venus Concept, Ltd.'s Venus Versa Substantial Equivalence Charts

Substantial Equivalence Table #1 for IPL Applicators: (1) SR515; (2) SR580; (3) HR650; (4) HR690; (5)HR650XL; (6) HR690XL; (7) ACDUAL

Medical Device	Venus Concept Ltd.'s Venus Versa System – Full Configuration	Danish Dermatologic Development A/S Ellipse I^2PL System (K060516)	Mattioli Pulse TWO/THREE Plus Family (K100053)	Global Medical Technology S.L.'s Platinum GMT IPL System Cloud (K140668)
Class, Product Code, Regulation	Class II ONF, GEX 21 CFR 878.4810	Class II, GEX, 21 CFR 878.4810	Class II, ONF, 21 CFR 878.4810	Class II, ONF, 21 CFR 878.4810
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.	Ellipse I^2PL System is intended for use in dermatology: * Hair removal (permanent hair reduction). * Treatment of benign pigmented lesions (including, but not limited to solar lentigines, ephilides, mottled pigmentation) and benign vascular lesions (including but not limited to diffuse redness, telangiectasias, port wine stains). * Treatment of inflammatory acne. *[Table included in indications for use form not included here, see Appendix 4 of 510(k)]*	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	The Platinum GMT™ IPL System Cloud device (inclusive of the hand piece used to deliver pulsed-light energy) is indicated for use in surgical, aesthetic and cosmetic applications in permanent hair reduction, moderate inflammatory acne vulgaris, benign cutaneous pigmented and vascular lesions. 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.

Medical Device	Venus Concept Ltd.'s Venus Versa System – Full Configuration	Danish Dermatologic Development A/S Ellipse I^2PL System (K060516)	Mattioli Pulse TWO/THREE Plus Family (K100053)	Global Medical Technology S.L.'s Platinum GMT IPL System Cloud (K140668)
	The HR650, HR690, HR650XL, and HR690XL 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. The Venus Concept ACDUAL applicator is intended to be used for the treatment of acne vulgaris.		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 anglormas, 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 nm for skin type V The equipment should only be used under medical supervision.	
Energy Type	IPL	IPL	IPL	IPL
IPL Spectrum	- Lesions: 515-950 nm (SR515); 580-950 nm (SR580) - Hair Removal: 650-950 nm (HR650, HR650XL); 690-950 nm (HR690, HR690XL)	400-950 - Lesions: ▪ Pigmented: 400-720 nm (PL) ▪ Vascular: 555-950 nm (VL); 530-750 nm (PR) - Hair Removal: 600-950nm	510-1200 nm - Lesions: 560-1200 nm (SA); 510-1200 nm (VA) - Hair Removal: 650-1200 nm (HN); 710-1200 nm (HF)	430-1200 nm - Lesions: 560-1200 nm ▪ Pigmented: 560-1200 nm ▪ Vascular: 560-1200 nm - Hair reduction: 695-1200

Medical Device	Venus Concept Ltd.'s Venus Versa System – Full Configuration	Danish Dermatologic Development A/S Ellipse I^2PL System (K060516)	Mattioli Pulse TWO/THREE Plus Family (K100053)	Global Medical Technology S.L.'s Platinum GMT IPL System Cloud (K140668)
	- Acne: 415 - 480 nm and 630 - 950 nm (ACDUAL)	(HR, HR-S); 645-950 nm (HR-D)		nm - Acne: 430-1200 nm
Frequency	Up to 3 Hz (SR, HR, HR XL) Up to 2 Hz (ACDUAL)	1.5-2.0 s charge time/repetition rate	Up to 1 Hz	1s, 2s, 3s repetition frequency
Spot Size	10 x 30 mm (SR 515, SR 580, HR650, HR690, ACDUAL) 20 x 30 mm (HR650XL, HR690XL)	10 x 48 mm	10 x 40 mm 15 x 50 mm	10 x 45 mm 8 x 34 mm
Pulse Duration	5-20 ms (SR515, SR580, ACDUAL); 20-50 ms (HR650, HR690, HR650XL, HR690XL).	1.5-100 ms	14-35 ms	1-9.9 ms - Lesions: ▪ Pigmented: 3-9 ms ▪ Vascular: 9.9 ms o Hair reduction: 9.9 ms Acne: 3-8 ms
Energy Density (Fluence)	Lesions/Acne (SR 515, SR 580, ACDUAL): 5-25 J/cm^2 Hair Removal (HR650, HR690, HR650XL, HR690XL): 5-20 J/cm^2	Max 26 J/cm^2 - Lesions: ▪ Pigmented: up to 18 J/cm^2 ▪ Vascular: up to 26 J/cm^2 - Hair Removal: up to 21 J/cm^2	Max 30 J/cm^2 - Skin Rejuvenation (SR): 6-30 J/cm^2 - Hair Removal (HR): 6-25 J/cm^2	Max 60 J/cm^2 - Lesions: ▪ Pigmented: 12-44 J/cm^2 ▪ Vascular: 10-50 J/cm^2 - Hair reduction: 10-60 J/cm^2 - Acne: 10-40 J/cm^2
Components	System console (with user interface) Applicators Ultrasonic gel	System console (with user interface) Applicators Optical coupling gel	System console (with user interface) Applicators	System console (with user interface) Applicators
Light guide	Sapphire light guide	Light guide	Crystal Light Guide	Sapphire light guide
Cooling system	Cooling system	Cooling system	Cooling system	Cooling system

Substantial Equivalence Table #2 for Bipolar RF and PMF Applicators: (1) Diamondpolar; (2) Octipolar

Medical Device	**Venus Concept Ltd.'s Diamondpolar and Octipolar Applicators**	**Venus Concept Ltd.'s Venus Legacy BX Device (K142910)**
Class, Product Code, Regulation	Class II, GEI, 21 CFR 878.4400	Class II, GEI, 21 CFR 878.4400
Intended Use / Indications for Use	The Diamondpolar and Octipolar applicators are non-invasive devices intended for use in dermatologic and general surgery procedures for females for the non-invasive treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin types I-IV.	The device is a non-invasive device intended for use in dermatologic and general surgery procedures for females for the non-invasive treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin types I-IV
Energy Type	Bipolar RF, PMF	Bipolar RF, PMF
Applicators	Diamondpolar Octipolar	Diamondpolar Octipolar
Maximum RF Output Power	Diamondpolar: 75 W Octipolar: 150 W	Diamondpolar: 75 W Octipolar: 150 W
RF Output Frequency	1 MHz	1 MHz
Magnetic Pulse Frequency	15 Hz	15 Hz
Magnetic Field	Up to 15 Gauss	Up to 15 Gauss

Substantial Equivalence Table #3 for Fractional RF Applicator: (1) Viva

Medical Device	**Venus Concept Ltd.'s Viva Applicator**	**Venus Concept Ltd.'s Viva SR Device (K150161)**
Class, Product Code, Regulation	Class II, GEI, 21 CFR 878.4400	Class II, GEI, 21 CFR 878.4400
Intended Use / Indications for Use	The Viva applicator is intended for dermatological procedures requiring ablation and resurfacing of the skin.	The Venus Viva SR System is intended for dermatological procedures requiring ablation and resurfacing of the skin.
Energy Type	Fractional RF	Fractional RF
(Maximum) RF Energy	62 mJ/pin	62 mJ/pin
Maximum RF Output Power	8 W	8 W
Applicator	Viva	Viva
Number of Pins	40 x 4 = 160 pins	40 x 4 = 160 pin
RF Output Frequency	0.46 MHz	0.46 MHz
Contact Area of Pin/ Active Area	133 mm^2	133 mm^2

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, IEC 60601-2-2, and IEC 60601-2-57. All results were passing. In addition, the patient contacting materials are biocompatible based on the established biocompatibility of the materials and per ISO 10993-5. The applicable cleaning, disinfection, and sterilization parameters have also been validated in testing.

The Venus Versa System also underwent software validation and verification, and results demonstrate that the software was appropriate for release.

System verification testing was performed on the subject Versa System with all 10 of the applicators. Results were all passing. Specifically, the Versa IPL applicators were tested to show that the measured fluence at each wavelength matches the expected value within the defined acceptance criterion. In addition, the light guide temperatures were also measured per the expected values. The measured fluence levels at each wavelength were within the expected values, demonstrating passing results for each applicator. Testing was conducted in increments of 5 J/cm^2 for a comprehensive evaluation across the range of fluence levels. The fluke measured temperatures of each applicator met specifications.

In addition, as previously submitted in K152790, the Venus Versa IPL applicators SR515, SR580, HR650, and HR690 were evaluated in spectrum testing. The Versa IPL applicators were measured using a spectrometer at each of the wavelengths. At each wavelength, the test results demonstrated that the spectral region is defined by the filter. Further, the ACDUAL applicator spectrum testing was also performed as part of the IEC 60601-2-57 testing.

For the Diamondpolar and Octipolar applicators, system verification testing showed that measured RF voltage, electromagnetic field density, and system temperature were within expected values and met the pass criteria. It should further be noted that the performance of these applicators were previously demonstrated in the company's cleared Legacy BX 510(k) (K142910).

For the Viva applicator, system verification testing showed that the measured output power (pulse width, pulse amplitude) was within expected values. In addition, the performance of the Viva applicator was previously demonstrated in the company's cleared Viva SR System 510(k) (K150161). As detailed in the report, system verification also ensured that the Versa applicators and system met technical and mechanical requirements. All results were passing.

Therefore, performance testing confirmed the equivalent technological characteristics and energy output available for the Versa compared to its predicate.

Substantial Equivalence

The Venus Versa has the same intended use and the same or similar indications for use, technological characteristics and principles of operation as its 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. As detailed above, the minor technological differences between the Venus Versa and its predicate devices do not raise any new types of safety or effectiveness questions, given that the key energy parameters (i.e., wavelengths, fluence levels, total energy) are the same or similar for the devices. Therefore, the Venus Versa System presents similar technological characteristics as its predicates, in support of substantial equivalence.

Conclusions

The Venus Versa has the same intended use and the same or similar indications for use, technological characteristics and principles of operation as its predicate devices. Testing demonstrates 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.