September 11, 2023

Venus Concept Inc.
℅ William Mcgrail
SVP Technical Operations & Compliance
Venus Concept USA Inc.
4001 SW 47th Ave, Suite 206
Davie, Florida 33314

Re: K232192
Trade/Device Name: Venus Versa PRO 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,GEI, GEX
Dated: August 9, 2023
Received: August 10, 2023

Dear William Mcgrail:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.09.11 12:30:57 -04'00'

Mark Trumbore, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Venus Versa PRO System

Indications for Use *(Describe)*

The Venus Versa PRO 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 longterm 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 MD 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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1. SUBMITTER

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Venus Concept
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Date Prepared: July 24, 2023

2. DEVICE INFORMATION

Trade/Device Name(s): Venus Versa PRO System

Regulation Number: 21 CFR § 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulation Class: Class II

Product Code: ONF, GEX, GEI

Review Panel: General & Plastic Surgery

3. PREDICATE DEVICES

	Device Name	510(k) Number
Predicate	Venus Versa System	K153717
Reference	Venus Viva MD Device	K201164

4. INDICATIONS FOR USE

The Venus Versa PRO 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 MD applicator is intended for dermatological procedures requiring ablation and resurfacing of the skin.

5. DEVICE DESCRIPTION

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

- Intense Pulsed Light (IPL)
  1) SR515
  2) SR580
  3) HR650
  4) HR690
  5) HR650XL
  6) HR690XL
  7) ACDUAL

- Magnetic Pulse (MP^2)
  1) Diamondpolar
  2) Octipolar

- Radiofrequency (RF)
  1) Viva MD (uses 80 and 160 disposable tips)

6. TECHNOLOGICAL CHARACTERISTICS

The Venus Versa PRO System has identical technological characteristics to its predicates. The Venus Versa PRO is a multi-application system that allows delivery of energy, similar to its predicates. The Versa PRO 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 PRO 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 and reference devices.

The technological differences between the Venus Versa PRO and its predicates are minor. An 80 pin tip, cleared in K201164 was added to the Viva applicator which increases the energy per pin to the skin and falls within the range of the predicate devices.

The technical differences between the Versa PRO and its predicates do not present any new or different issues of safety or effectiveness as the operation of the device and technological parameters are similar to those of the predicate. The Venus Versa PRO System presents similar technological characteristics as its predicates, in support of substantial equivalence. See Table 5-1 below.

7. TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The Venus Versa PRO System is substantially similar in intended use to the predicate device Venus Versa System and has similar technological characteristics as the reference device Venus Viva MD System.

The Venus Versa PRO System contains all the same hardware and technological characteristics of the Venus Versa predicate device. The changes between the Versa PRO and Versa are summarized below:

1. Addition of an 80 pin tip for the Viva MD applicator cleared on the reference device.
2. Updated software to recognize the 80 pin tip.

Tables 5-1 through 5-3 compare the intended use, key performance and technological features of the Venus Versa PRO System with the predicate device.

The Venus Viva MD system was chosen as Reference device since it uses the exact Viva MD applicator and 80 pin tip that is being added to the Venus Versa System and for the same indications for use.

Table 5-1: Substantial Equivalence Comparison with Predicate Device for IPL Applicators: 1) SR515; 2) SR580; 3) HR650; 4) HR690; 5) HR650XL; 6) HR690XL; 7) ACDUAL

Product	Venus Versa PRO System (Subject)	Venus Versa System (Predicate)	Similarities and significant differences to the predicate device
Class, Product Code, Regulation	Class II, ONF, GEX, 21 CFR 878.4810	Class II, ONF, GEX, 21 CFR 878.4810	Identical
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.	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.	Identical

Product	Venus Versa PRO System (Subject)	Venus Versa System (Predicate)	Similarities and significant differences to the predicate device
	· 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.	· 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.	
Energy Type	IPL	IPL	Identical
IPL Spectrum	- Lesions: 515-950 nm (SR515); 580-950 nm (SR580) - Hair Removal: 650-950 nm (HR650, HR650XL); 690-950 nm (HR690, HR690XL) - Acne: 415 - 480 nm and 630 - 950 nm (ACDUAL)	- Lesions: 515-950 nm (SR515); 580-950 nm (SR580) - Hair Removal: 650-950 nm (HR650, HR650XL); 690-950 nm (HR690, HR690XL) - Acne: 415 - 480 nm and 630 - 950 nm (ACDUAL)	Identical
Frequency	Up to 3 Hz (SR, HR, HR XL) Up to 2 Hz (ACDUAL)	Up to 3 Hz (SR, HR, HR XL) Up to 2 Hz (ACDUAL)	Identical
Spot Size	10 x 30 mm (SR 515, SR 580, HR650, HR690, ACDUAL) 20 x 30 mm (HR650XL, HR690XL)	10 x 30 mm (SR 515, SR 580, HR650, HR690, ACDUAL) 20 x 30 mm (HR650XL, HR690XL)	Identical
Pulse Duration	5-20 ms (SR515, SR580, ACDUAL); 20-50 ms (HR650, HR690, HR650XL, HR690XL).	5-20 ms (SR515, SR580, ACDUAL); 20-50 ms (HR650, HR690, HR650XL, HR690XL).	Identical
Energy Density (Fluence)	Lesions/Acne (SR 515, SR 580, ACDUAL):	Lesions/Acne (SR 515, SR 580, ACDUAL):	Identical

Product	Venus Versa PRO System (Subject)	Venus Versa System (Predicate)	Similarities and significant differences to the predicate device
	5-25 J/cm^2 Hair Removal (HR650, HR690, HR650XL, HR690XL): 5-20 J/cm^2	5-25 J/cm^2 Hair Removal (HR650, HR690, HR650XL, HR690XL): 5-20 J/cm^2	
Components	System console (with user interface) Applicators Ultrasonic gel	System console (with user interface) Applicators Ultrasonic gel	Identical
Light guide	Sapphire light guide	Sapphire light guide	Identical
Cooling system	Cooling system	Cooling system	Identical

Table 5-2: Substantial Equivalence Comparison with Predicate Device for Bipolar RF and PMF Applicators: 1) Diamondpolar; 2) Octipolar

Product	Venus Versa PRO System (Subject)	Venus Versa System (Predicate)	Similarities and significant differences to the predicate device
Class, Product Code, Regulation	Class II, GEI, 21 CFR 878.4400	Class II, GEI, 21 CFR 878.4400	Identical
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 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.	Identical
Energy Type	Bipolar RF, PMF	Bipolar RF, PMF	Identical
Applicators	Diamondpolar Octipolar	Diamondpolar Octipolar	Identical
Maximum RF Output Power	Diamondpolar: 75 W Octipolar: 150 W	Diamondpolar: 75 W Octipolar: 150 W	Identical
RF Output Frequency	1 MHz	1 MHz	Identical
Magnetic Pulse Frequency	15 Hz	15 Hz	Identical
Magnetic Field	Up to 15 Gauss	Up to 15 Gauss	Identical

Table 5-3: Substantial Equivalence Comparison with Predicate and Reference Devices for Fractional RF Applicator: 1) Viva MD

Product	Venus Versa PRO System (Subject)	Venus Versa System (Predicate)	Venus Viva MD System (Reference)	Similarities and significant differences to the predicate device
Class, Product Code, Regulation	Class II, GEI, 21 CFR 878.4400	Class II, GEI, 21 CFR 878.4400	Class II, GEI, 21 CFR 878.4400	Identical
Intended Use / Indications for Use	The Viva MD applicator is intended for dermatological procedures requiring ablation and resurfacing of the skin.	The Viva applicator is intended for dermatological procedures requiring ablation and resurfacing of the skin.	The Viva MD applicator is intended for dermatological procedures requiring ablation and resurfacing of the skin.	Identical
Energy Type	Fractional RF	Fractional RF	Fractional RF	Identical
(Maximum) RF Energy	62 mJ/pin - 160 pin tip **124 mJ/pin - 80 pin tip**	62 mJ/pin - 160 pin tip	62 mJ/pin - 160 pin tip 124 mJ/pin - 80 pin tip	Different for Predicate. Same as Reference.
Maximum RF Output Power	8 W	8 W	8W	Identical
Energy Density	7.5 J/cm^2	7.5 J/cm^2	7.5 J/cm^2	Identical
Applicator	Viva MD	Viva	Viva MD	Identical
Tip Number of Pins	- 40 x 4 = 160 pins **- 40 x 2 = 80 pins**	40 x 4 = 160 pins	- 40 x 4 = 160 pins - 40 x 2 = 80 pins	Different for Predicate. Same as Reference.
RF Output Frequency	0.46 MHz	0.46 MHz	0.46 MHz	Identical
Contact Area of Pin/ Active Area	133 mm^2	133 mm^2	133 mm^2	Identical
Materials	− Plastic (Makrolon 2458) − Stainless Steel tip pin electrodes	− Plastic (Makrolon 2458) − Stainless Steel tip pin electrodes	− Plastic (Makrolon 2458) − Stainless Steel tip pin electrodes	Identical

SUBSTANTIAL EQUIVALENCY AND COMPARISON OF TECHNOLOGICAL SIMILARITIES & DIFFERENCES

As described in the comparison tables above, the Venus Versa PRO subject device has an identical intended use and indications for use, identical technological characteristics, and principles of operation as its predicate and reference devices. There are no technological differences between the Venus Versa PRO device and its predicate and reference devices, so there are no new issues of safety or effectiveness.

The design and components in the Venus Versa PRO device, including the console and the applicators are identical to the design and components found in the predicate and the reference devices Venus Versa, K153717, (console and applicators) and Venus Viva MD, K201164 (viva applicator and 80 pin tip).

8. PERFORMANCE DATA

8.1 Summary of Non-Clinical Performance Testing

- Electrical Safety: The added changes to the system do not affect the previous test results of IEC 60601-1 Medical electrical equipment, General requirements for Safety.
- Electromagnetic Interference (EMC): The added changes to the system do not affect the previous test results for IEC 60601-1-2.
- Bench Testing: A bench test was performed to verify that the 80 pin tip delivers the same output power as the predicate device.
- Software: Software verification and validation testing has been performed and passed the expected results. In all instances, the device functioned as intended and the results observed were as expected.
- Biocompatibility: The 80 pin tip has the same product material as in the predicate device.

8.2 Clinical Performance Data

Based on the similarities in the safety and effectiveness profiles of the subject and the predicate, no clinical studies were deemed needed to support this submission.

9. CONCLUSION

The Venus Versa PRO System is as safe and effective as its predicate device, Venus Versa, cleared under K153717. The modified system has the same intended use and indications, similar technological characteristics, and similar principle of operation as its predicate device. The above discussed slight modifications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. Thus, the Venus Versa PRO System is substantially equivalent to its predicate.