November 6, 2025

Venus Concept Inc.
Danielle Fulk
Manager, Regulatory Affairs
1800 Bering Drive
San Jose, California 95112

Re: K252845
Trade/Device Name: Venus Nova (FP-2001)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, PBX, NGX
Dated: August 28, 2025
Received: September 8, 2025

Dear Danielle Fulk:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2025.11.06 09:57:43 -05'00'

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

Please provide the device trade name(s).

Venus Nova (FP-2001)

Please provide your Indications for Use below.

The Venus Nova device is intended for the treatment of the following medical conditions using the 4D Body (MP2) applicator for delivery of RF energy combined with massage and magnetic field pulses:
• Relief of minor muscle aches and pain, relief of muscle spasm
• Temporary improvement of local blood circulation
• Temporary reduction in the appearance of cellulite

When used with the Octipolar (LB1) or Diamondpolar (LFI) applicators, the Venus Nova device is intended for use in dermatologic and general surgical procedures for females for the non-invasive treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin types I-IV.

In addition, the Venus Nova device using the FlexMAX applicators is intended for muscle conditioning to stimulate healthy muscles.

The Venus Nova device using the FlexMAX applicators is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind.

The Venus Nova device using the FlexMAX applicators is intended to be operated by a trained professional.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY
(As Required by 21.CFR.807.92)

1. SUBMITTER

Manufacturer: Venus Concept, Inc.
1800 Bering Drive
San Jose, CA 95112, USA

Contact Person: Danielle Fulk
Manager, Regulatory Affairs
Venus Concept
Phone: (240) 422-0399
Email: dfulk@venus.ai

Date Prepared: July 23, 2025

2. DEVICE INFORMATION

Trade/Device Name(s): Venus Nova

Regulation Number: 21 CFR § 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulation Class: Class II

Product Code: GEI, PBX, NGX

Review Panel: General & Plastic Surgery

3. PREDICATE DEVICES

	Device Name	510(k) Number
Predicate	Venus BlissMAX	K220592
Secondary Predicate	Venus Legacy Pro - Octipolar Applicator - Diamondpolar Applicator	K191528

510(K) SUMMARY

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4. INDICATIONS FOR USE

The Venus Nova device is intended for the treatment of the following medical conditions using the 4D Body (MP2) applicator for delivery of RF energy combined with massage and magnetic field pulses:

- Relief of minor muscle aches and pain, relief of muscle spasm
- Temporary improvement of local blood circulation
- Temporary reduction in the appearance of cellulite

When used with the Octipolar (LB1) or Diamondpolar (LF1) applicators, the Venus Nova device is intended for use in dermatologic and general surgical procedures for females for the non-invasive treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin types I-IV.

In addition, the Venus Nova device using the FlexMAX applicators is intended for muscle conditioning to stimulate healthy muscles.

The Venus Nova device using the FlexMAX applicators is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind.

The Venus Nova device using the FlexMAX applicators is intended to be operated by a trained professional.

5. DEVICE DESCRIPTION

The Venus Nova device is a computerized device comprised of a console (main unit), one (1) 4D Body applicator containing RF, PEMF and Vacuum, one (1) Octipolar applicator for large anatomical areas containing RF and PEMF, one (1) Diamondpolar applicators for smaller anatomical areas containing RF and PEMF and four (4) FlexMAX applicators containing Electrical Muscle Stimulation (EMS). The device delivers bipolar RF and biphasic electrical energies, vacuum pressure, and pulsed electromagnetic fields (PEMF) to the skin and the underlying tissues of the treatment area. The device provides individual adjustment of EMS intensity level, and RF power, in addition to vacuum levels, for each patient.

The console of the Venus Nova device contains a power supply unit, RF and EMS controllers, (power modules, on main board), a suction module (vacuum), a controller unit (on main board), a touch- screen user interface and display panel.

The applicators are connected to the console via cables. The RF applicators are comprised of various combinations of RF electrodes, magnetic coils, and vacuum conduits. The EMS applicators are comprised of two electrodes each and a light indicator.

510(K) SUMMARY

6. TECHNOLOGICAL CHARACTERISTICS

The Venus Nova device using the RF applicators provides RF treatments combined with emitted magnetic fields and vacuum massaging. The Vacuum is mainly used for the massaging of deep tissues by creating mild to deep suction. The vacuum massage improves the contact surface between electrodes and tissue. The RF currents heat the adipose and muscular tissues to trigger tissue level changes leading to temporary reduction in the appearance of cellulite and temporary relief of muscle pain and muscle spasm. The RF heating effect also improves local blood circulation in the sub dermal layers. The PEMF assists in achieving treatment effect.

Furthermore, the Venus Nova device using the FlexMAX (EMS) applicators contracts muscles by passing electrical currents through electrodes contacting the affected body area. The transcutaneous electrical current is designed to affect underlying, healthy muscles, causing them to contract. The FlexMAX applicators are coupled to the patient's body while using a dedicated belt during the entire treatment. The belt size and number of EMS applicators is determined by the treatment area and its size. Its use on muscles is in accordance with a class II device Powered Electrical Muscle Stimulator (Product Code NGX), based on the FDA guidance document for powered muscle stimulators for muscle conditioning as a special control.

The Nova device has identical technological characteristics to its predicate and Secondary Predicate devices.

7. TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The Venus Nova device is substantially similar in intended use to the predicate Venus BlissMAX device and the Secondary Predicate Venus Legacy Pro device and has similar technological characteristics as both the predicate Secondary Predicate devices.

The Venus Nova device contains most of the same hardware and technological characteristics of the Venus BlissMAX predicate device. The significant changes between the Venus Nova and the Venus BlissMAX devices are summarized below:

1. Removal of the four diode applicators used on the Venus BlissMAX device.
2. Addition of the RF applicators Octipolar and Diamondpolar cleared on the Venus Legacy Pro device.
3. Updated software to recognize the Octipolar and Diamondpolar RF applicators.
4. 4D Body applicator name changed from MP2 to 4D Body.
5. Color was changed from white to black

6. The system on module (SOM) was updated to a new version to allow for WiFi connectivity to a cloud, replacing the cellular component utilized in the predicate device.

Tables 1 through 3 compare the intended use, key performance and technological features of the Venus Nova device with the predicate and Secondary Predicate devices.

The Venus BlissMAX device was chosen as predicate device since it includes the same indications for use as well as the technological characteristics for the Venus Nova device. The Secondary Predicate device was chosen since it uses the exact Octipolar and Diamondpolar applicators that are being added to the Venus Nova device.

Table 1: Substantial Equivalence Table for the 4D Body (RF+ PEMF +Vacuum) Applicator

Product	Venus Nova (Subject)	Venus BlissMAX (Predicate)	Similarities and significant differences
Class, Product Code, Regulation	Class II, PBX, 21 CFR 878.4400 21 CFR 878.5400	Class II, PBX, 21 CFR 878.4400 21 CFR 878.5400	Identical
Intended Use / Indications for Use	The Venus Nova device is intended for the treatment of the following medical conditions; using the 4D Body (MP2) applicator for delivery of RF energy combined with massage and magnetic field pulses: • Relief of minor muscle aches and pain, relief of muscle spasm • Temporary improvement of local blood circulation • Temporary reduction in the appearance of cellulite.	The Venus BlissMAX device is intended for the treatment of the following medical conditions; using the MP2 applicator for delivery of RF energy combined with massage and magnetic field pulses: • Relief of minor muscle aches and pain, relief of muscle spasm • Temporary improvement of local blood circulation • Temporary reduction in the appearance of cellulite.	Identical
Energy Use/Delivered	1. RF Energy 2. Pulsed ElectroMagnetic Field (PEMF) 3. Vacuum	1. RF Energy 2. Pulsed ElecroMagnetic Field (PEMF) 3. Vacuum	Identical
Applicators	4D Body (MP2)	MP2	Identical
Frequency	1 MHz	1 MHz	Identical
Maximum RF Output Power	Up to 150W	Up to 150W	Identical
PEMF Power	15 Gauss (15Hz)	15 Gauss (15Hz)	Identical
Electrical Power	100-120 VAC / 60Hz 220-240 VAC / 50Hz	100-120 VAC / 60Hz 220-240 VAC / 50Hz	Identical

510(K) SUMMARY

Product	Venus Nova (Subject)	Venus BlissMAX (Predicate)	Similarities and significant differences
Vacuum Pressure	-400mbar	-400mbar	Identical

Table 2: Substantial Equivalence for the Electrical Muscle Stimulation (EMS) Applicators

Product	Venus Nova (Subject)	Venus BlissMAX (Predicate)	Similarities and significant differences
Class, Product Code, Regulation	Class II, NGX, 21 CFR 890.5850	Class II, NGX, 21 CFR 890.5850	Identical
Intended Use / Indications for Use	The Venus Nova device using the FlexMAX applicators is intended for muscle conditioning to stimulate healthy muscles. The Venus Nova device using the FlexMAX applicators is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. The Venus Nova device using the FlexMAX applicators is intended to be operated by a trained professional.	The Venus BlissMAX device using the FlexMAX applicators is intended for muscle conditioning to stimulate healthy muscles. The Venus BlissMAX device using the FlexMAX applicators is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. The Venus BlissMAX device using the FlexMAX applicators is intended to be operated by a trained professional.	Identical
Mechanism of Action	Muscle contraction by electrical pulsing.	Muscle contraction by electrical pulsing.	Identical
Electrical Power	Main Line Frequency (nominal): 50-60Hz Input Voltage (nominal): 100-240VAC	Main Line Frequency (nominal): 50-60Hz Input Voltage (nominal): 100-240VAC	Identical
Method of Line Current Isolation	Power Supply isolation	Power Supply isolation	Identical
Patient Leakage Current	Normal condition: 1 µA Single Fault condition: 11 µA	Normal condition: 1 µA Single Fault condition: 11 µA	Identical
Number of Output Modes	1	1	Identical
Number of Output Channels	4	4	Identical

510(K) SUMMARY

Product	Venus Nova (Subject)	Venus BlissMAX (Predicate)	Similarities and significant differences
Channel Output: Synchronous or Alternating	Synchronous	Synchronous	Identical
Output Specifications			
Waveform	Symmetrical Biphasic waveform	Symmetrical Biphasic waveform	Identical
Shape	Rectangular	Rectangular	Identical
Maximum Output Voltage	40V@500Ω 105V@2kΩ 160V@10kΩ	40V@500Ω 105V@2kΩ 160V@10kΩ	Identical
Maximum Output Current	80 mA @ 500 Ω 52.5 mA @ 2 kΩ 16 mA @ 10 kΩ	80 mA @ 500 Ω 52.5 mA @ 2 kΩ 16 mA @ 10 kΩ	Identical
Frequency range	1 Hz to 1000 Hz	1 Hz to 1000 Hz	Identical
Pulse width range	500 to 2500 [µs]	500 to 2500 [µs]	Identical
Net Charge	0 [µC] @ 500Ω Zero net charge is achieved by using symmetrical biphasic waveforms	0 [µC] @ 500Ω Zero net charge is achieved by using symmetrical biphasic waveforms	Identical
Maximum Phase Charge	40 [µC] @ 500Ω @ 1000 Hz	40 [µC] @ 500Ω @ 1000 Hz	Identical
Maximum Current Density	2.5 mA/cm2	2.5 mA/cm2	Identical
Maximum Power Density	55 [mW/cm2] @500Ω	55 [mW/cm2] @500Ω	Identical

Table 3: Substantial Equivalence for the Octipolar and Diamondpolar (RF+PEMF) Applicators

Product	Venus Nova (Subject)	Venus Legacy Pro (Secondary Predicate)	Similarities and significant differences
Class, Product Code, Regulation	Class II, GEI & PBX, 21 CFR 878.4400	Class II, GEI & PBX, 21 CFR 878.4400	Identical
Indications for Use	When used with the Octipolar (LB1) or Diamondpolar (LF1) applicators, the Venus Nova device is intended for use in dermatologic and general surgical procedures for females for the non-invasive treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin types I-IV.	When used with the Octipolar (LB1) or Diamondpolar (LF1) applicators, the Venus Legacy Pro device is intended for use in dermatologic and general surgical procedures for females for the noninvasive treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin types I- IV. When used with the 4D Body (LB2) and 4D Face (LF2) applicators, the Venus Legacy Pro device is intended for the delivery of non-thermal RF combined with Massage and magnetic field pulses for the treatment of the following medical conditions: • Relief of minor muscles aches and pain, relief of muscle spasm • Temporary improvement of local blood circulation • Temporary reduction in the appearance of cellulite	Similar
Energy Use/Delivered	1. RF Energy 2. Pulsed ElectoMagnetic Field (PEMF)	1. RF Energy 2. Pulsed ElectroMagnetic Field (PEMF)	Identical
Applicators	Diamondpolar, Octipolar	Diamondpolar, Octipolar	Identical
Anatomical Sites	Body and Face	Body and Face	Identical
Frequency	1 MHz	1 MHz	Identical
Maximum RF Output Power	Octipolar up to 150W Diamondpolar up to 75W	Octipolar up to 150W Diamondpolar up to 75W	Identical
PEMF Power	15 Gauss (15Hz)	15 Gauss (15Hz)	Identical

Product	Venus Nova (Subject)	Venus Legacy Pro (Secondary Predicate)	Similarities and significant differences
Electrical Power	100-120 VAC / 60Hz 220-240 VAC / 50Hz	100-120 VAC / 60Hz 220-240 VAC / 50Hz	Identical

SUBSTANTIAL EQUIVALENCY AND COMPARISON OF TECHNOLOGICAL SIMILARITIES & DIFFERENCES

As described in the comparison tables above, the Venus Nova device has similar indications for use and technological characteristics as the predicate and Secondary Predicate devices.

The Venus Nova devices' technological characteristics are identical to the core technologies used in the predicate device. The Octipolar and Diamondpolar applicators being added to the Venus Nova device are identical to the applicators used on the Secondary Predicate device. Both the predicate and Secondary Predicate devices have been cleared by the FDA for use on humans for their respective indications for use.

The technological characteristics of the Venus Nova core technology and performance have been addressed by the performance and software validation testing. These performance tests demonstrate that the Venus Nova is safe and effective and does not raise any new issues regarding safety and effectiveness.

The inclusion of updated connectivity in the Venus Nova has been assessed and evaluated according to robust software and cybersecurity testing and risk evaluation. These activities demonstrate that all risks associated with the use of wireless connectivity to a cloud have been appropriately mitigated such that there are no unacceptable risks associated with the safe and effective use of Venus Nova.

The design and components in the Venus Nova, including the console and the applicators are identical to the design and components found in the predicate and the Secondary Predicate devices Venus BlissMAX device K220592 (console, RF and EMS applicators) and Venus Legacy Pro device K191528 (Octipolar and Diamondpolar applicators).

8. PERFORMANCE DATA

8.1 Summary of Non-Clinical Performance Testing

- Electrical Safety: The added changes to the device 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 device do not affect the previous test results for IEC 60601-1-2.

- Bench Testing: A bench test was performed to verify that the Octipolar and Diamondpolar RF applicators deliver the same output power as the predicate and Secondary Predicate devices.
- 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 Octipolar and Diamondpolar RF applicators have the same product material as in the as the FDA cleared Secondary Predicate device.
- Cybersecurity: Full cybersecurity testing has been performed to mitigate all unacceptable residual risks to meet the new cybersecurity requirements issued by the FDA since the Predicate and Secondary Predicate devices were cleared.

8.2 Clinical Performance Data

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

9. CONCLUSION

The Venus Nova device is as safe and effective as its predicate and Secondary Predicate devices, Venus BlissMAX device, cleared under K220592 and Venus Legacy Pro device, cleared under K191528. The modified device has the same intended use and indications, similar technological characteristics, and similar principle of operation as its predicate and Secondary Predicate devices. The above discussed 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 Nova is substantially equivalent to its predicate.