April 27, 2022

Venus Concept USA Inc.
William Mcgrail
VP, Global Regulatory Affairs & Quality Assurance
1880 N Commerce Pkwy, Suite 2
Weston, Florida 33326

Re: K220592
Trade/Device Name: Venus BlissMAX
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX, PKT, NGX
Dated: February 24, 2022
Received: March 1, 2022

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,

Purva Pandya, D.Eng.
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)*
K220592

Device Name
Venus BlissMAX

Indications for Use *(Describe)*
The Venus BlissMAX device is a diode laser system intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs in individuals with a Body Mass Index (BMI) of 30 or less.

In addition, 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

In addition, 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.

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
(As Required by 21.CFR.807.92)

1. SUBMITTER

Manufacturer:	Venus Concept USA, Inc. 1880 N Commerce Pkwy, Suite 2 Weston, FL 33326, USA
Contact Person:	William H. McGrail Vice President, Global RA & QA Venus Concept Phone: (978) 808-0420 Email: bmcgrail@venusconcept.com
Date Prepared:	April 27, 2022

2. DEVICE INFORMATION

Trade/Device Name(s):	Venus BlissMAX System
Common or Unusual Name:	Venus BlissMAX System
Regulation Number:	21 CFR § 878.4400 21 CFR § 878.5400 21 CFR § 890.5850
Classification Name:	Electrosurgical Cutting And Coagulation Device And Accessories
Regulation Class:	Class II
Product Code:	PKT, PBX, NGX,
Review Panel:	General & Plastic Surgery

3. PREDICATE DEVICES

Primary Predicate:	Venus Concept Venus BlissMAX (K213308)
Co-Secondary Predicate:	Cynosure SculpSure (K182741)
Co-Secondary Predicate:	Venus Concept Venus Legacy Pro (K191528)

4. INDICATIONS FOR USE

The Venus BlissMAX device is a diode laser system intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs in individuals with a Body Mass Index (BMI) of 30 or less.

In addition, 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

In addition, 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

5. DEVICE DESCRIPTION

The Venus BlissMAX device is a computerized system comprised of a system console (main unit), four (4) Diode Laser applicators, one (1) MP^2 (RF+ PEMF+ Vacuum) applicator and four (4) FlexMAX (EMS) applicators. The system delivers laser, 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 laser power, EMS intensity level, and RF power, in addition to vacuum levels, for each patient.

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

The applicators are connected to the console via a cable. The RF applicator is comprised of various combinations of RF electrodes, magnetic coils, and vacuum conduits.

The Laser applicators are comprised of a light guide, touch sensors and light-emitting diodes.

The EMS applicator is comprised of two electrodes and a light indicator.

6. TECHNOLOGICAL CHARACTERISTICS

The Venus BlissMAX device delivers laser energy to the subcutaneous tissue layers via the four diode laser applicators connected to the console. The console utilizes diode laser modules as sources of optical energy and the optical output is fiber-coupled through the applicator to the treatment area. The laser applicators are coupled to the patient's body while using a dedicated belt for the entire treatment. Individual adjustment of the laser output power is provided for each applicator to achieve maximum safety and efficiency for the patient. The laser applicators have an integrated contact skin cooling system to enhance safety and comfort of the treatment.
In addition, the Venus BlissMAX device using the MP2 applicator 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 BlissMAX device using the FlexMAX applicators (EMS applicators) contracts muscles by passing electrical currents through electrodes contacting the affected body area. The transcutaneous electrical current is designed to effect 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[1].

7. TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following tables compare the Venus BlissMAX (Subject) device to the primary predicate: Venus BlissMAX (K213308) and co-secondary predicate: Cynosure SculpSure Laser System (K182741) and co-secondary predicate: Venus Legacy Pro (K191528) devices with respect to intended use, technological characteristics, and principles of operation, providing detailed information regarding the basis for the determination of substantial equivalence.

[1] The Guidance for Industry, FDA Reviewers/Staff and Compliance Guidance Document for Powered Muscle Stimulator 510(k)s issued on June 9, 1999

Table 1: Substantial Equivalence Table for the Diode Laser Applicators

	Venus BlissMAX (Subject)	**Venus BlissMAX (K213308) (Primary Predicate)**	**SculpSure Laser System (K182741) (Co-Secondary Predicate)**	**Substantial Equivalence Discussion**
Manufacturer	Venus Concept	Venus Concept	Cynosure Inc.	Same as Primary Predicate Device
Classification Product Code, Regulation	Class II, PKT, 21 CFR 878.5400	Class II, PKT 21 CFR 878.5400	Class II, PKT, 21 CFR 878.5400	Same as both
Indications for Use	The Venus BlissMAX device is a diode laser system intended for non-invasive lipolysis of the abdomen, flanks, **back**, and **thighs** in individuals with a Body Mass Index (BMI) of 30 or less.	The Venus BlissMAX device is a diode laser system intended for non-invasive lipolysis of the abdomen and flanks in individuals with a Body Mass Index (BMI) of 30 or less.	The SculpSure is intended for non-invasive lipolysis of the abdomen, flanks, **back**, and **thighs** in individuals with a Body Mass Index (BMI) of 30 or less. In addition, the device is intended for non-invasive lipolysis of the submental area in individuals with a BMI of 49 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen, flanks, back, thighs and submental area. When using the petite mask for non-invasive lipolysis of the submental area, the device can also affect the appearance of lax tissue in the submental area.	Same as Co-secondary Predicate and Primary predicate Devices
Lipolysis Method	Heat-assisted	Heat-assisted	Heat-assisted	Same as both
Energy Used / Delivered	Diode Laser	Diode Laser	Diode Laser	Same as both
Components	Console with GUI 4 Applicators - Sapphire light guides - LED contact sensors	Console with GUI 4 Applicators - Sapphire light guides - LED contact sensors	Console with GUI 4 Applicators - Sapphire light guides - LED contact sensors	Same as both
Wavelength	1064 ± 10nm (infrared)	1064 ± 10nm (infrared)	1060 ± 20nm (infrared)	Same as both
Spot Size	6 x 6 cm^2 on each of the Applicator heads	6 x 6 cm^2 on each of the Applicator heads	4 x 6 cm^2 on each of the Applicator heads	Same as Primary predicate Device
Operation Mode	CW	CW	CW	Same as both

	Venus BlissMAX (Subject)	Venus BlissMAX (K213308) (Primary Predicate)	SculpSure Laser System (K182741) (Co-Secondary Predicate)	Substantial Equivalence Discussion
Power Density	Up to 1.4 W/cm^2	Up to 1.4 W/cm^2	Up to 1.4 W/cm^2	Same as both
Attachment to Patient	Belt	Belt	Belt	Same as both
Power Requirements	100-240V~50/60 Hz, Single Phase	100-240V~50/60 Hz, Single Phase	100-240V~50/60 Hz, Single Phase	Same as both
Materials	Biocompatible	Biocompatible	Biocompatible	Same as both
Sterility	Non-sterile	Non-sterile	Non-sterile	Same as both

Table 2: Substantial Equivalence Table for the MP2 (RF+ PEMF +Vacuum) Applicators

	Venus BlissMAX (Subject)	Venus BlissMAX (K213308) (Primary Predicate)	Venus Legacy Pro (K191528) (Co-Secondary Predicate)	Substantial Equivalence Discussion
Manufacturer	Venus Concept	Venus Concept	Venus Concept	Same as both
Classification 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	Class II, GEI, PBX 21 CFR 878.4400	Same as both
Indications for Use	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.	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.	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	Same as Primary predicate Device and similar to the Co-Secondary Predicate.

	Venus BlissMAX (Subject)	Venus BlissMAX (K213308) (Primary Predicate)	Venus Legacy Pro (K191528) (Co-Secondary Predicate)	Substantial Equivalence Discussion
			pain, relief of muscle spasm • Temporary improvement of local blood circulation • Temporary reduction in the appearance of cellulite	
Energy Used / Delivered	1. RF Energy 2. Pulsed Magnetic Field (PMF) 3. Vacuum	1. RF Energy 2. Pulsed Magnetic Field (PMF) 3. Vacuum	1. RF Energy 2. Pulsed Magnetic Field (PMF) 3. Vacuum	Same as Primary predicate
Applicator Footprint Dimensions	MP^2: 38.5 cm^2	MP^2: 38.5 cm^2	LB1: 23.7 cm2 LF1: 2.9 cm2 LB2: 38.5 cm2 LF2: 4.9 cm2	Same as Primary predicate
Performance	Frequency: 1MHz Vacuum pressure: -400mbar Maximal RF output power: up to **150W** PMF Power: 15 Gauss (15Hz)	Frequency: 1MHz Vacuum pressure: -400mbar Maximal RF output power: up to 100W PMF Power: 15 Gauss (15Hz)	Frequency: 1MHz Vacuum pressure: -400mbar Maximal RF output power: up to **150W** PMF Power: 15 Gauss (15Hz)	Same as Co-Secondary Predicate device
Materials	Biocompatible	Biocompatible	Biocompatible	Same as both
Power Requirements	100-120 VAC / 60Hz 220-240 VAC / 50Hz	100-240V~50/60 Hz, Single Phase	100-120 VAC / 60Hz 220-240 VAC / 50Hz	Same as both

Table 3: Substantial Equivalence Table for the FlexMAX (EMS) Applicators:

	Venus BlissMAX (Subject)	Venus BlissMAX (K213308) (Primary Predicate).	Substantial Equivalence Discussion
Basic Unit Characteristics			
Classification Product Code, Regulation	Class II, NGX, 21 CFR 890.5850,	Class II, NGX, 21 CFR 890.5850	Same
Indications for Use	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.	The Venus BlissMAX deviceusing the FlexMAX applicators is intended for muscle conditioning to stimulate healthy muscles. The Venus BlissMAX deviceusing 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 deviceusing the FlexMAX applicators is intended to be operated by a trained professional.	Same
Components	The Venus BlissMAX device consists of the following components: • Console, including a power supply unit, controller and user interface including an LCD touch screen. • Several types of applicatorsfor different indications (Laser, MP^2, FlexMAX applicators) connected to theconsole via a cable.	The Venus BlissMAX device consists of the following components: • Console, including a power supply unit, controller and user interface including an LCD touch screen. • Several types of applicatorsfor different indications (Laser, MP^2, FlexMAX applicators) connected to theconsole via a cable.	Same
Mechanism of Action	Muscle contraction by electrical pulsing.	Muscle contraction by electrical pulsing.	Same
Power Source	Main Line Frequency (nominal): 50-60Hz Input Voltage (nominal): 100-240VAC	Main Line Frequency (nominal): 50-60Hz Input Voltage (nominal): 100-240VAC	Same
Method of Line Current Isolation	Power Supply isolation	Power Supply isolation	Same
Patient Leakage Current	Normal condition:1 µA Single Fault condition:11 µA	Normal condition:1 µA Single Fault condition:11 µA	Same
Number of Output Modes	1	1	Same

Number of Output Channels	4	4	Same
Channel Output: Synchronous or Alternating	Synchronous	Synchronous	Same
Method of channel isolation	Isolation transformer per channel	Isolation transformer per channel	Same
Regulated Current or Regulated Voltage	Regulated voltage with current limit	Regulated voltage with current limit	Same
Software/ Firmware/ Microprocessor Control	Yes	Yes	Same
Automatic EMS Shut off	Yes- Automatic EMStreatment shut off	Yes- Automatic EMStreatment shut off	Same
Patient Override Control	Yes- Emergency button	Yes- Emergency button	Same
Indicator Display:On / Off Status	Yes	Yes	Same
Indicator Display: Voltage Current Level	Yes	Yes	Same
Timer Range	Selectable 15, 30, 45, 60 min	Selectable 15, 30, 45, 60 min	Same
Weight	62 Kg / 136.7 lbs	62 Kg / 136.7 lbs	Same
Dimensions	21.7 x 25.6 x 53.2 in 55 x 65 x 135 cm	21.7 x 25.6 x 53.2 in 55 x 65 x 135 cm	Same
Output Specifications			
Waveform	Symmetrical Biphasicwaveform	Symmetrical Biphasicwaveform	Same
Shape	Rectangular	Rectangular	Same
Maximum Output Voltage	40V@500Ω 105V@2kΩ 160V@10kΩ	40V@500Ω 105V@2kΩ 160V@10kΩ	Same
Maximum Output Current	80 mA @ 500 Ω 52.5 mA @ 2 kΩ 16 mA @ 10 kΩ	80 mA @ 500 Ω 52.5 mA @ 2 kΩ16 mA @ 10 kΩ	Same
Frequency range	1 Hz to 1000 Hz	1 Hz to 1000 Hz	Same
Pulse width range	500 to 2500 [µs]	500 to 2500 [µs]	Same

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	Same
Maximum Phase Charge	40 [µC] @ 500Ω @ 1000 Hz	40 [µC] @ 500Ω @ 1000 Hz	Same
Maximum Current Density	2.5 mA/cm^2	2.5 mA/cm^2	Same
Maximum Power Density	55 [mW/cm^2] @500Ω	55 [mW/cm^2] @500Ω	Same

8. SUBSTANTIAL EQUIVALENCY AND COMPARISON OF TECHNOLOGICAL SIMILARITIES & DIFFERENCES

As described in the comparison tables above, the Venus BlissMAX subject device has the same intended use and indications for use, similar technological characteristics, and principles of operation as its primary predicate and co-secondary predicate devices. The technological differences between the Venus BlissMAX device and its primary predicate and co-secondary devices do not raise any new issues of safety or effectiveness. The Venus BlissMAX device and its primary predicate device Venus Concept's Venus BlissMAX (K213308) and its co-secondary predicate devices the Venus Concept Venus Legacy Pro (K191528) and Cynosure SculpSure (K182741) are based on the same core technologies of Diode Laser (as in the Venus BlissMAX and Cynosure SculpSure), RF along with PEMF and vacuum massaging (as in the Venus BlissMAX and the Venus Legacy Pro), and EMS technology (as in the Venus BlissMAX) for the same indications for use. The design and components in the Venus BlissMAX device, including the console and the applicators are similar to the design and components found in the primary predicate and the co-secondary predicate devices.

The technological differences do not alter the device's core technology or performance and have been addressed by the manufacturer through the applicable safety standards (General controls and mitigation measures) and through non-clinical performance testing (Special controls).

9. PERFORMANCE DATA

Verification and Validation tests have been performed to show that the performance specifications of Venus BlissMAX system is the same as the primary predicate and co-secondary predicate devices. As MP^2 applicator is identical to the primary predicate and co-secondary predicate devices, the Bench test that was conducted in Legacy demonstrates that the use of 150W is considered to be safe. Testing to IEC 60601-1 and IEC 60601-1-2 has been conducted on the Venus BlissMAX System. All performance testing demonstrated that the Venus BlissMAX System performs according to specifications and functions as intended.

The following non-clinical testing was performed on the Venus BlissMAX System. These tests verified that the Venus BlissMAX System was identical to the primary predicate and co-secondary predicate devices.

Electrical Safety and Electromagnetic Compatibility: Electrical safety and electromagnetic compatibility (EMC) testing for the Venus BlissMAX System was conducted by an independent test laboratory in accordance with IEC 60601-1, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance and with IEC 60601-1-2, Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
The Venus BlissMAX System was determined to be in conformance with applicable IEC standards (IEC 62366, IEC 60601-1 and IEC 60601-1-2).

The Venus BlissMax was also determined to be in conformance with the following electrical and safety testing:
IEC 60601-2-2 :2017 ed 6 Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.

EN 60601-2-22:2007+A1:2012 Particular requirements for basic safety and essential performance of laser equipment.

IEC 60601-2-10:2012+A1:2016 Particular requirements for the basic safety and essential performance of nerve and muscle stimulator.

IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements.

IEC 60601-1-6: 2013 ed 3 General requirements for basic safety and essential performance - Collateral standard: Usability.

Software: Software verification testing was conducted, and results demonstrated that testing results were found acceptable for software release. Software testing was performed per FDA's guidance document "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices".

Biocompatibility

The patient-contacting components of the device were demonstrated to be biocompatible including evaluation of cytotoxicity, irritation, and sensitization, acute systemic toxicity and material-mediated pyrogenicity per the FDA guidance document "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Clinical Testing

No Clinical testing was performed.

10. SUBSTANTIAL EQUIVALENCE SUMMARY

The Venus BlissMAX System is the same device and has the same technological characteristics as the primary device: Venus BlissMAX (K213308) and co-secondary predicate: Venus Legacy Pro Legacy Pro (K191528) and has the same intended use and indications as the co-secondary

predicate device: Cynosure SculpSure (K182741). Thus, the Venus BlissMAX System is Substantially equivalent to its predicate devices.

11. CONCLUSION

The performance testing data demonstrates that Venus BlissMAX System is as safe and effective as the legally marketed primary predicate and co-secondary predicate devices. The Venus BlissMAX System did not raise new questions of safety or effectiveness. Therefore, based on the information provided in this Premarket Notification, we conclude that Venus BlissMAX System has demonstrated substantial equivalence to the predicate devices and the performance testing data support the indications for use.