December 20, 2022

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

Re: K221011
Trade/Device Name: AI.ME System
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling Device For Aesthetic Use
Regulatory Class: Class II
Product Code: QAI
Dated: November 17, 2022
Received: November 17, 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,

Jessica Carr -S

for Long Chen, 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)*

K221011

Device Name
AI.ME System

Indications for Use *(Describe)*
The AI.ME™ system is indicated for fractional skin resurfacing.

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, Inc.
1800 Bering Drive
San Jose, CA 95112, USA

Contact Person: William H. McGrail
Vice President, Global RA & QA
Venus Concept
Phone: (978) 808-0420
Email: bmcgrail@venusconcept.com

Date Prepared: December 19, 2022

2. DEVICE INFORMATION

Trade/Device Name(s): AI.ME™ System
Regulation Number: 21 CFR § 878.4430
Regulation Name: Microneedling device for aesthetic use
Regulation Class: Class II
Product Code: QAI
Review Panel: General And Plastic Surgery Devices

3. PREDICATE DEVICES

	Device Name	510(k) Number
Predicate	Cytrellis Dermal Micro-Coring System (Ellacor)	K202517
Reference #1	Fraxis DUO System	K160312
Reference #2	ARTAS IX System	K173358

4. INDICATIONS FOR USE

The AI.ME system is indicated for fractional skin resurfacing.

5. DEVICE DESCRIPTION

The AI.ME system is a micro coring device controlled by a robot that removes skin by using a disposable punch assembly containing six (6), hollow needle punches inserted into the skin with a fixed maximum penetration depth of 3 mm to remove up to 10% of skin in the treatment area to excise and/or resurface skin.

The AI.ME system, which is similar in design and performance as the FDA cleared Venus Concept ARTAsystem, consists of a cart, a coring mechanism, single-use vacuum assembly and a sterile single-use disposable punch assembly.

6. TECHNOLOGICAL CHARACTERISTICS

The AI.ME system consists of a cart, a robotic arm with an integrated imaging system, vacuum assembly, coring mechanism, and punch assembly. The robot arm provides precision skin coring to the treatment area preventing possibility of retreating an area and causing possible damage to the skin and underlying tissue. The cart consists of a real time controller and an embedded computer for the system software, a touch screen user interface, power suppliers and circuit controllers. These major components used on the Venus Concept ARTAS (K173358) reference device are the same. The coring mechanism, which is permanently attached to the end of the robot arm, consists of actuation elements to advance, retract, and spin the punch assembly. The disposable punch assembly is connected to the end of the coring mechanism. The disposable vacuum assembly consists of a skin accumulation chamber with the input connected via tubing to the punch assembly used to remove skin from each of the six needles using vacuum prior to the robot inserting thepunches into the skin at the next location in the treatment are. The punch assembly consists of six (6) hollow 0.74 mm in diameter cylindrical shape needles with a sharp conical cutting tip at the top arranged in a hexagon pattern. The punch assembly and coring mechanism is designed to prevent anyfluids from ingress into the coring mechanism to prevent cross contamination. The needles rotate at 4500 RPM while the coring mechanism moves the needle punch assembly in and out of the skin also at 4500 RPM before moving to the next skin treatment location.

7. TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The Cytrellis Biosystems, Inc. Ellacor system was chosen as the predicate device since the Ellacor device contains similar micro coring technological characteristics to the AI.ME system. Both the Ellacor and AI.ME perform micro coring of the skin using stainless steel hollow needles to remove 8% to 10% of skin. Both systems have the same product code.

Table 5-1 compares the intended use, key performance and technological features of the AI.ME System with the predicate device.

The Ilooda Co., Ltd FRAXIS DUO system was chosen as reference #1 device since the AI.ME system indications for use is a subset of the indications for use of the FRAXIX DUO system. Both systems perform fractional skin resurfacing.

The Venus Concept USA, Inc. ARTAX IX system was chosen as reference #2 device since the AI.ME system uses the same major components as the ARTAS IX system which was cleared by the FDA. Both systems use a robotic arm, imaging system, coring mechanism and needle punch assembly to remove skin or hair follicles from the body.

Table 5-1 Substantial Equivalence Comparison Table with Predicate Device

Product	AI.ME System (Subject)	Ellacor System (Predicate)	Similarities and significant differences to the predicate device
Device Classification name	Microneedling Device For Aesthetic Use	Microneedling Device For Aesthetic Use	Identical
Device Product Code	QAI	QAI	Identical
Device Class	Class II	Class II	Identical
Regulation Number	21 CFR 878.4430	21 CFR 878.4430	Identical
Indications for Use	The AI.ME system is indicated for fractional skin resurfacing.	The Cytrellis® Dermal Micro-Coring™ System is indicated for use by medical professionals for the treatment of moderate and severe wrinkles in the mid and lower face in adults aged 22 years or older with Fitzpatrick skin types I-IV.	Similar Both devices are used in aesthetic procedures in dermatology. Both devices are for the treatment of skin. The proposed indication being sought in this 510(K) is for fractional skin resurfacing. Animal testing and performance data provided demonstrates that the AI.ME System is safe and effective for the indication and intended use described and does not pose any undue or additional risks.
Geometry	6 hollow needles, hexagon arrangement	Single (1) needle or three (3) hollow needles arranged in a straight line. Needles are ground to 10-degree tip angle resulting in two (2) cutting services and two (2) tips	Dissimilar Animal testing similar to the predicate device and non-clinical performance testing demonstrates that the AI.ME device does not pose any undue or additional risks and is effective.

Product	AI.ME System (Subject)	Ellacor System (Predicate)	Similarities and significant differences to the predicate device
Maximum needle penetration (maximum needle length)	Fixed 3 mm core depth	Up to 4.0mm core depth setting or 5mm needle tip depth	Dissimilar Animal testing similar to the predicate device and non-clinical performance testing demonstrates that the AI.ME device does not pose any undue or additional risks and is effective.
Needle protrusion setting	Fixed 3 mm core depth	0-4.0mm core depth setting or 1-5mm needle tip depth	Dissimilar Animal testing similar to the predicate device and non-clinical performance testing demonstrates that the AI.ME device does not pose any undue or additional risks and is effective.
Percentage Tissue Removal	Up to 10%	Up to 7.9%	Dissimilar Animal testing similar to the predicate device and non-clinical performance testing demonstrates that the AI.ME device does not pose any undue or additional risks and is effective.
Treatment Protocol	At least 2 but no more than 3 treatments spaced 4 weeks apart	At least 2 but no more than 3 treatments spaced 4 weeks apart	Identical
Delivery System	Robotic Arm with punch assembly	Handheld instrument	Dissimilar Animal testing similar to the predicate device and non-clinical performance testing demonstrates that the AI.ME device does not pose any undue or additional risks.
Needle Diameter	0.74 mm	< 0.50 mm	Dissimilar Animal testing similar to the predicate device and non-clinical performance testing demonstrates that the AI.ME device does not pose any undue or additional risks and is effective. The

Product	AI.ME System (Subject)	Ellacor System (Predicate)	Similarities and significant differences to the predicate device
			subject device needle diameter is larger..
Puncture Rate	6 punctures/6 seconds	24-36 punctures/second	Dissimilar Animal testing similar to the predicate device and non-clinical performance testing demonstrates that the AI.ME device does not pose any undue or additional risks and is effective. The puncture rate of the subject device is significantly less than the predicate.

SUBSTANTIAL EQUIVALENCY AND COMPARISON OF TECHNOLOGICAL SIMILARITIES & DIFFERENCES

As described in the comparison tables above, the AI.ME subject device has a similar intended use and indications for use, similar technological characteristics, and principles of operation as its predicate and reference devices. The technological differences between the AI.ME device and its predicate and reference devices do not raise any new issues of safety or effectiveness. The AI.ME device has similar indication for use as Fraxis DUO System (K160312) fractional skin resurfacing and same core technology as ARTAS IX and Cytrellis Dermal Micro-Coring System (Ellacor) (202517). The design and components in the AI.ME device, including the console and the accessories are similar to the design and components found in the predicate and the reference devices ARTAS IX (robotic arm, console and computer items) and Cytrellis Dermal Micro-Coring System (Ellacor) (202517) (coring and punching kits).

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).

Furthermore, the AI.ME device underwent performance testing, including software validation testing, electrical safety and electromagnetic compatibility testing. These performance tests in addition to the bench test demonstrated that the differences in the technological characteristics between the subject's predicate and reference devices do not raise new types of safety or effectiveness concerns.

8. PERFORMANCE DATA

8.1 Summary of Non-Clinical Performance Testing

The following performance and safety testing has confirmed the proposed device to be substantially equivalent to the predicate device:

- Software: Documentation was prepared and submitted for a moderate level of concern device in accordance with FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

- Electrical Safety: The AI.ME System has been tested and successfully passed all the relevant sections of IEC 60601-1 Medical electrical equipment, General requirements for Safety.

- Electromagnetic Interference (EMC): The AI.ME has been tested and successfully met all of the relevant sections (Radiated emissions, Conducted emissions, Harmonic emissions, Flicker emissions, Electrostatic discharge immunity test, radiated radio frequency immunity, Electrical fast transient/burst, lightning surge immunity, conducted RF immunity, electromagnetic field immunity, voltage dips and short interruptions, RFID compatibility, and power frequency magnetic field immunity test) to satisfy compliance with IEC 60601-1-2.

To demonstrate safety and effectiveness and support substantial equivalence, the AI.ME System has undergone non-clinical performance testing in line with recognized standard: The Guidance for Industry and FDA Administration Staff; Regulatory Considerations for Microneedling Products issued on November 10, 2020.

(1) The technical specifications and needle characteristics have been identified, including needle length, geometry, maximum penetration depth, and puncture rate.		
(2) Non-clinical performance data demonstrates that the device performs as intended under anticipated conditions of use. The following performance characteristics have been tested:		
(i)	Accuracy of needle penetration depth and puncture rate	Accuracy of needle penetration depth and puncture rate was tested in a suitable skin substrate model and measured using the Keyence Laser System
(ii)	Safety features built into the device to protect against cross-contamination & fluid ingress protection	The device design prevents cross contamination including fluid ingress protection due to the needle cartridge design. Design elements include serialized disposable assemblies that are entered into the system software prior to use.to prevent needle cartridge re-use and a sealed path to prevent fluid ingress. Testing was performed under worst case scenarios.

(iii)	Identification of the max safe needle penetration depth for the device & for the labeled indications for use	Maximum safe needle penetration depth was identified in a suitable skin substrate model. The needle depth is fixed at 3 mm and can not be adjusted thus eliminating the needle depth hazard.
(3) Performance data must demonstrate the sterility of the patient-contacting components of the device.		Performance data demonstrates the sterility of the patient-contacting components of the device according to ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ISO 14937.
(4) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the intended shelf life.		Disposables are supplied non-sterile and are sterilized per a validated procedure prior to use. Materials are non-degradable and therefore a labeled shelf life is not required.
(5) Performance data must demonstrate the electrical safety and electromagnetic compatibility (EMC) of all electrical components of the device.		Performance data demonstrates the electrical safety and electromagnetic compatibility (EMC) of all electrical components of the device according to IEC 60601-1 and IEC 60601-1-2.
(6) Software verification, validation, and hazard analysis must be performed for all software components of the device.		Software verification, validation, and hazard analysis were performed for all software components of the device according to in accordance with FDA's Guidance for the *Content of Premarket Submissions for Software Contained in Medical Devices*
(7) The patient-contacting components of the device must be demonstrated to be biocompatible.		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 an pyrogenicity per ISO 10993-1
(8) Performance data must validate the cleaning and disinfection instructions for reusable components of the device.		A cleaning and disinfection validation was performed for reusable components of the device per AAMI TIR30.
(9) Labeling includes the following:		
(i)	Information on how to operate the device and its components and the typical course of treatment;	
(ii)	A summary of the device technical parameters, including needle length, needle geometry, maximum penetration depth, and puncture rate;	
(iii)	Validated methods and instructions for reprocessing of any reusable components;	
(iv)	Disposal instructions; and	
(v)	A shelf life	
(10) Patient labeling includes:		
(i)	Information on how the device operates and the typical course of treatment;	
(ii)	The probable risks and benefits associated with use of the device;	

(iii)	Postoperative care instructions.

8.2 Pre-Clinical (Animal) Performance Data

A pre-clinical study using swine model was conducted using micro coring of the skin. The evaluation included macroscopic and histopathological analysis of different predetermined parameters of treated area and depth and width of the skin excision areas post treatment; 7 days post treatment; 14 days post treatment and 28 days post treatment. Overall, the macroscopical and the histopathological evaluation of the AI.ME system, showed a clear time-related progressive process of healing, post the skin tissue excision and towards a full resurfacing of the treated area.

Conclusion: The pre-clinical study emphasizing the swine-model, showed that the AI.ME system does not pose any undue or additional risks and is safe and effective for fractional skin resurfacing.

9. CONCLUSION

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