September 27, 2022

ILOODA Co., Ltd
% Dave Kim
Medical Device Regulatory Affairs
Mtech Group
7505 Fannin St. Ste 610
Houston, Texas 77054

Re: K212561
Trade/Device Name: Mtx-c1
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: July 22, 2022
Received: August 1, 2022

Dear Dave Kim:

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,

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)*
K212561

Device Name
MTX-C1

Indications for Use *(Describe)*

The MTX-C1 is intended for the treatment of the following medical condition; using three types of handpieces for delivery of non-thermal RF combined with massage:
• Relief of minor muscle aches and pain, relief of muscle spasm
• Temporary improvement of local blood circulation
• Temporary reduction in the appearance of cellulite

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Traditional 510(k) Summary
K212561

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510k summary prepared: 9/19/2022

I. SUBMITTER

Submitter's Name :	Ilooda Co.,Ltd
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Contact person:	Yun-Jung HA (yjha@ilooda.com) / RD Manager
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Telephone:	+713-467-2607

PROPOSED DEVICE	
Trade/proprietary name:	MTX-C1
Common or Usual Name:	Electrosurgical cutting and coagulation device and accessories
Regulation Number:	21 CFR 878.4400 (Product Code: PBX)
Regulatory Class:	Class II
Prescription Use.	

PREDICATE DEVICE	
Trade/proprietary name:	Venus Legacy CX
510k number:	K143554
Regulation Number:	21 CFR 878.4400 (Product Code: PBX)
Regulatory Class:	Class II
Prescription Use.	

This predicate has not been subject to a design-related recall.

II. DEVICE DESCRIPTION

The MTX-C1 main unit is a RF(Radio-frequency) energy generator employed for a variety of aesthetic applications. The Main unit output is set and monitored via touchscreen and controlled by a footswitch.
The main unit can be used with 3 different types of handpieces for treatment.

The system consists of ;
1) Main unit
2) 3 type treatment handpiece
3) Footswitch
4) Touch screen(User interface)
The three treatment handpieces differ in size and configuration and are indicated for the treatment of various size areas.
The operator can adjust treatment parameters such as the power level and treatment time from the user interface on the Main Unit.
The handpiece is applied with a rubbing/massaging technique and the applicator should be moved continuously on the skin.

III. INDICATIONS FOR USE:

The MTX-C1 is intended for the treatment of the following medical condition; using three types of handpieces for delivery of non-thermal RF combined with massage:

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

IV. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Proposed device	Predicated device
Model name	MTX-C1	Venus Legacy CX
Manufacturer	Ilooda Co,.Ltd	Venus Concept Ltd.,Weston FL, USA
510(k)number	K212561	K143554
Product code	PBX	PBX
Intended use	The MTX-C1 is intended for the treatment of the following medical condition; using three types of handpieces for delivery of non-thermal RF combined with massage: • 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 Legacy CX device is intended for the treatment of the following medical conditions; using the LB2 and LF2 applicators for delivery of non-thermal RF 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
Type of Energy Delivered	RF energy	RF energy
Components	Main unit 3 type handpieces (Small, Medium, Large) Footswitch Touch screen	Main unit 2 type applicators (LB2, LF2) Footswitch / finger switch Touch screen
User interface	Touchscreen on front of the generator allows the user to select mode and output	Touchscreen on front of the generator allows the user to select mode and output
Safey features	- Indicator(Ready/Standby) - An independent electronic circuit stops the operation of the system in case of a software error.	Applicators are equipped with a treatment area temperature monitoring system
Frequency	1MHz ± 10%	1MHz ± 10%
Max power	Max 55W @ medium , Large Max 7.5W @ small	Up to 150W
RF mode of operation	Bipolar	Bipolar
Materials	Materials are biocompatible	Materials are biocompatible
Power requirements	100-240V~, 50/60Hz	100-120 VAC / 60Hz 220-240 VAC / 50Hz

As described in the comparison tables above, the MTX-C1 subject device has the same intended use and indications for use, principles of operation and similar technological characteristics such as type of energy delivered, user interface, frequency, RF mode of operations, as its predicate

device.

The technological differences, for example, the max power outputs between the subject device and its predicate, are based on the same heating using radio frequency for the same indications for use.

The design and components in the subject device, including the main unit and the handpieces, are similar to the design and components found in the predicate device.
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 bench testing (Skin temperature)

Thus, this does not raise any additional issues of safety and efficacy.

V. PERFORMANCE DATA

The following performance data was provided in support of the substantial equivalence determination.

Biocompatibility testing:
The patient contact components and materials are tested and validated according to ISO10993-1. They are identical to the predicate device.

Non Clinical testing:
IEC 60601-1 Test for Medical Electrical Equipment was performed for General Requirements for basic safety and essential performance. The requirements of specified standards were fulfilled.
IEC 60601-1-2 Test for Medical Electrical Equipment was performed for General Requirements for basic safety and essential performance (collateral standards: electromagnetic compatibility.
IEC 60601-2-2 Medical electrical equipment
Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

The requirements of specified standards were fulfilled.

Performance bench testing :
The three handpieces of MTX-C1 were tested to achieve superficial skin temperature (40 - 45°C) and maintain it for the required therapy time.
The testing data demonstrated that the device can achieve therapeutic parameters substantially equivalent to the currently cleared predicate device for the intended use.

VI. CONCLUSIONS

The intended use of the MTX-C1 is within the scope of the predicate device.
MTX-C1 system, from both a design and clinical perspective, uses similar or identical technology as the cited predicate device and has the same intended uses.

Based upon the predicted overall performance characteristics for the MTX-C1, Ilooda Co.,Ltd ., believes that no significant differences exist in the usage of its underlying technological principles between MTX-C1 and the cited predicate device.