June 29, 2022

Guangzhou CHUANG ZAO MEI Technology Co., Ltd
℅ Asher No Last Name Provided
Regulatory Affairs Manager
AskWay Innovative Ltd.
4F, Yuehuayuan Building, 2008 Nanshan Avenue, Nanshan Street
Nashan District
Shenzhen, Guangdong 518000
China

Re: K221312
Trade/Device Name: Diode Laser Hair Removal Device
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: GEX
Dated: April 29, 2022
Received: May 5, 2022

Dear Asher No Last Name Provided:

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 and Part 809); 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,

Jianting Wang
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

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)*
K221312

Device Name
Diode Laser Hair Removal Device

Indications for Use *(Describe)*
The Diode Laser Hair Removal Device (Model: EVOLUTION MEDICAL, M-I-X MEDICAL) is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin.
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 regime.

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

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER

Guangzhou CHUANG ZAO MEI Technology Co., Ltd.

Dehe international A505, No.2, Qixinggang Industrial Road, JUNHE street, Baiyun District, Guangzhou

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Date Prepared: 06/21/2022

II. SUBMISSION CORRESPONDENT

Primary Contact Person: Asher
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Secondary Contact Person: Albert Ou
General Manager
AskWay Innovative Ltd.
Phone: 086-(0) 13751890680
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III. PROPOSED DEVICE

Trade Name:	Diode Laser Hair Removal Device
Common Name:	Powered Laser Surgical Instrument
Model(s):	EVOLUTION MEDICAL, M-I-X MEDICAL
Classification Name:	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology (21 CFR 878.4810)
Regulation Class:	II
Product Code:	GEX
Review Panel:	General & Plastic Surgery

IV. PREDICATE DEVICE

510(k) Number:	K210663
Device Name:	Dermatological Diode Laser Systems
Manufacturer:	Beijing HuaCheng Taike Technology Co., Ltd.

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

V. DEVICE DESCRIPTION

The Diode Laser Hair Removal Device is a surgical device intended for use in dermatologic and general surgical procedure. It utilizes a diode laser as a laser source (808 nm). The laser power is delivered to the treatment area via a laser handpiece. The emission laser is activated by a foot switch and a laser handpiece.

There are two models included, EVOLUTION MEDICAL, M-I-X MEDICAL, the two models have same mechanism of action, principle and specification, with only one difference: the adjustable range of Energy density is different, EVOLUTION MEDICAL (1-77 J/cm^2), M-I-X MEDICAL (1-70 J/cm^2).

VI. INDICATIONS FOR USE

The Diode Laser Hair Removal Device (Model: EVOLUTION MEDICAL, M-I-X MEDICAL) is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin.
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 regime.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Diode Laser Hair Removal Device (EVOLUTION MEDICAL, M-I-X MEDICAL) is the same or similar to the cleared predicate device.

The Diode Laser Hair Removal Device (EVOLUTION MEDICAL, M-I-X MEDICAL) has same indications for use with the predicate device, and similar technological characteristics such as fluence, laser wavelength, spot size, and pulse duration, etc. with the predicate device. Please refer to the following table for details:

Item	Proposed Device K221312	Predicate Device K210663	Remark
Device name	Diode Laser Hair Removal Device	Dermatological Diode Laser Systems	/
Product model	EVOLUTION MEDICAL/ M-I-X MEDICAL	CM01D/CM02D	/
K number	K221312	K210663	/
Product code	GEX	GEX	Same
Classification regulation	21 CFR 878.4810	21 CFR 878.4810	Same
Class	2	2	Same
Indications for Use	The Diode Laser Hair removal device (Model: EVOLUTION MEDICAL, M-I-X MEDICAL) is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. 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 regime.	The Dermatological Diode Laser Systems (Model: CM01D/CM02D) is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. 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 regime.	Same
Prescription use or not	Prescription use	Prescription use	Same
Configuration	Main Unit	Main Unit	Same
	Handpiece	Handpiece	Same

Item	Proposed Device K221312	Predicate Device K210663	Remark
	Foot Control	Foot Control	Same
Principle of Operation	Diode laser	Diode laser	Same
Laser Type	Diode laser	Diode laser	Same
Laser Classification	Class IV	Class IV	Same
Laser Wavelength	808 nm	808 nm	Same
Spot size	12.6mm*20.6mm	CM01D: 10 x 30 mm CM02D: 9 x 12 mm	Similar
Fluence	EVOLUTION MEDICAL: 1-77 J/cm^2 M-I-X MEDICAL: 1-70 J/cm^2	CM01D: 5-100 J/cm^2 CM02D: 3-30 J/cm^2	Similar
Frequency	1-10 Hz	CM01D: 1-10 Hz CM02D: 1-3 Hz	Same
Pulse Duration	3-320 ms	CM01D: 15-400 ms CM02D: 35-400 ms	Similar
Power Supply	AC 120V/60 Hz	AC 110V/60Hz	Similar
Dimension	393mm x 430mm x 1130mm	CM01D: 650mm x 650mm x 1230mm CM02D: 252mm x 210mm x 193mm	/
Weight	48kg	CM01D: 75kg CM02D: 3kg	/

Analysis:

The proposed device is slightly different in spot size, fluence range, pulse duration, power supply, dimension, and weight from the predicate device. Spot size, fluence range, pulse duration can all be covered by predicate device, the differences in power supply, dimension and weight can be accepted by complying with the non-clinical test conducted. Therefore, these differences will not affect the safety and effectiveness, and the proposed device is determined to be the same or similar with predicate device.

Item	Proposed Device K221312	Predicate Device K210663	Remark
EMC, Electrical and Laser Safety			
Electrical Safety	Comply with ANSI/AAMI ES60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	Same

Item	Proposed Device K221312	Predicate Device K210663	Remark
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Laser Safety	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	Same
Patient Direct/Indirect Contact Materials and Biocompatibility			
Patient Direct/Indirect Contact Materials	Tip of Handle (6063 Aluminum & S1 Quartz)	Tip of Handle (6061 Aluminum &Quartz) Device Housing (Acrylonitrile Butadiene Styrene)	Same
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Sensitization	No evidence of sensitization	No evidence of sensitization	Same
Irritation	No evidence of irritation	No evidence of irritation	Same
Biocompatibility testing standards	Comply with ISO 10993-5, ISO 10993-10	Comply with ISO 10993-5, ISO 10993-10	Same

VIII. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was the same or similar to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ANSI/AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text), Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

IEC 60601-2-22 Edition 3.1 2012-10, Medical Electrical Equipment - Part 2-22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment.

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

ISO 10993-5 Third Edition 2009-06-01, Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity. (Biocompatibility)

ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization. (Biocompatibility)

Performance Testing for Energy Output Accuracy.

Software Verification and Validation Testing was conducted per “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”, and the level of concern was determined to be Moderate for the proposed device.

IX. CLINICAL TEST CONCLUSION

No clinical study is included in this submission.

X. CONCLUSIONS

Based on the comparison and analysis above, the proposed device is determined to be as safe, as effective, and performs as well as the predicate device.