November 19, 2020

Shenzhen Leaflife Technology Co., Ltd
Albert Ou
Regulatory Affairs Manager
Bldg. C, JMD Industrial Park, No.39 Qingfeng Blvd.,
Baolong Industrial Area, Longgang District
Shenzhen, Shenzhen 518116
China

Re: K202980
Trade/Device Name: Laser Therapy 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: September 27, 2020
Received: September 30, 2020

Dear Albert Ou:

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,

Purva Pandya
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202980

Device Name
Laser Therapy Device

Indications for Use *(Describe)*
The Laser Therapy Device 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

Shenzhen Leaflife Technology Co., Ltd

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Date Prepared: 11/18/2020

II. PROPOSED DEVICE

Trade Name:	Laser Therapy Device
Common Name:	Powered Laser Surgical Instrument
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

III. PREDICATE DEVICE

Predicate device 1#	Diode Laser Hair Removal System, Model HM-DL100: K162659, Manufacturer: Shandong Huamei Technology Co., Ltd
Predicate device 2#	Diode laser hair removal device, Model PZ-806NVA: K180353, Manufacturer: Zhengzhou PZ Laser Slim Technology Co., Ltd

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

IV. DEVICE DESCRIPTION

The Laser Therapy 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 hand piece. The emission laser is activated by a foot switch and a hand piece. The components of the Laser Therapy Device are mainly including main unit, hand piece, watered cup, overflow tube, foot switch, key, interlock, power cord, fuse, glasses and blindfold, etc.

The proposed Laser Therapy Device is equipped with laser depilation function that is based on the theory of selective photo thermolysis. There is abundant melanin in hair follicle and hair stem. The melanin is distributed amidst the cells between the hair ball substrate and it can be transferred to the structure of hair stems (such as medulla, cortex and hair cuticle). The laser can precisely target at the melanin and apply the depilation treatment selectively. After the melanin absorbs laser energy, the temperature rises, in this way, the surrounding hair follicle tissues are damaged, and the hairs are removed.

V. INDICATIONS for USE

The Laser Therapy Device 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Laser Therapy Device (LM-L808A) has same intended use, and technological characteristics such as fluence, laser wavelength, spot size, and pulse duration, etc. with the predicates. Please refer to the following table for details:

Item	Proposed Device	Predicate Device K162659	Predicate Device K180353	Remark
Device name	Laser Therapy Device	Diode Laser Hair Removal System	Diode laser hair removal device	/
Product model	LM-L808A	HM-DL100	PZ-806NVA	/
K number	On pending	K162659	K180353	/
Product code	GEX	GEX	GEX	SE
Classification regulation	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	SE
Intended Use	The Laser Therapy Device 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 Diode Laser System 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 Diode Laser Hair Removal device 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.	SE
Prescription use or not	Prescription use	Prescription use	Prescription use	SE
Configuration	Main Unit	Main Unit	Main Unit	SE
	Hand piece	Handpiece	Handpiece	SE

Item	Proposed Device	Predicate Device K162659	Predicate Device K180353	Remark
	Foot Control	Foot Control	Foot Control	SE
Principle of Operation	Diode laser	Diode laser	Diode laser	SE
Laser Type	Diode laser	Diode laser	Diode laser	SE
Laser Classification	Class IV	Class IV	Class IV	SE
Laser Wavelength	808 nm	808 nm	808 nm	SE
Spot size	1.44cm^2	1.44cm^2	1.44cm^2	SE
Irradiance	360 W/cm^2	0.7-347.8 W/cm^2	14-360 W/cm^2	SE
Fluence	1-100J/cm^2	1-120J/cm^2	1-100J/cm^2	SE
Frequency	1-10Hz	0.5-15Hz	1-20Hz	Discussion
Pulse Duration	5-400ms	5-400ms	10-400ms	SE
Power Supply	AC 220~240V 50/60 Hz or AC 100~120V 50/60 Hz	AC 110V/60Hz	AC 110V-230V/50-60Hz 2000VA	Discussion
Dimension	650mm x 430mm x 315mm	450mm x 550mm x 380mm	560mm x 380mm x 1180mm	Discussion
Weight	22kg	52kg	60kg	Discussion

Discussion

The proposed device is different in frequency range, power supply, dimension and weight from the predicate device.

Item	Proposed Device	Predicate Device K162659	Predicate Device K180353	Remark
Patient Contact Materials and Biocompatibility				
Patient Contact Materials	Sapphire in handpiece	Sapphire in handpiece	Sapphire in handpiece	SE
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	No Cytotoxicity	SE
Sensitization	No evidence of sensitization	No evidence of sensitization	No evidence of sensitization	SE
Irritation	No evidence of irritation	No evidence of irritation	No evidence of irritation	SE
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	Comply with IEC 60601-1, IEC 60601-2-22	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Laser Safety	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	SE

VII. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) 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, 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 Spot Size Accuracy and 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.

VIII. CLINICAL TEST CONCLUSION

No clinical study is included in this submission.

IX. CONCLUSION

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