April 12, 2022

Shenzhen Leaflife Technology Co., Ltd
Cheng Qiang
Regulatory registration supervisor
4F,Bldg. C, JMD Industrial Park, No.39 Qingfeng Blvd.,
Baolong Industrial Area, Longgang Dist.,
Shenzhen, Guangdong 518116
China

Re: K220103
Trade/Device Name: LED Therapy Device (Planar LED/Planar LED mini)
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: OHT
Dated: January 6, 2022
Received: January 12, 2022

Dear Cheng Qiang:

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
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)*
K220103

Device Name
LED Therapy Device (Planar LED/ Planar LED mini)

Indications for Use *(Describe)*
The LED 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

I. SUBMITTER

Shenzhen Leaflife Technology Co., Ltd

4F, Bldg. C, JMD Industrial Park, No.39 Qingfeng Blvd., Baolong Industrial Area,

Longgang Dist., Shenzhen, RP China

Phone: 086-(0)17875910506

Fax: 086-0755-27215592

Primary Contact Person:

Cheng Qiang

Regulatory Affairs Manager

Shenzhen Leaflife Technology Co., Ltd

Tel: 086-0755-27216609

Fax: 086-0755-27215592

Phone: 086-(0)17875910506

Email: cq@leaflife.cn

Date Prepared: 01/06/2022

II. PROPOSED DEVICE

Trade Name:	LED Therapy Device
Common Name:	Powered Laser Surgical Instrument
Classification Name:	Powered Laser Surgical Instrument (21 CFR 878.4810)
Regulation Class:	II
Product Code:	OHT
Review Panel:	General & Plastic Surgery

III. PREDICATE DEVICE

Predicate device (Primary)	Laser Therapy Device, Model LM-L808A: K202980
Predicate device	TRIA Laser Hair Removal System, Model TRIA: K120737
Predicate device	IPL Salon Hair Reduction System, Model F60001: K181568

The predicates have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The LED Therapy Device is a surgical device intended for use in dermatologic and general surgical procedure. It utilizes a diode LED as a light source (780-850 nm). The LED light power is delivered to the treatment area via a LED hand piece. The emission LED is activated by a foot switch and a hand piece.

The proposed LED Therapy Device is equipped with a light depilation function that is based on the theory of selective photo thermolysis. There is abundant melanin in the 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 Near infrared light can precisely target the melanin and apply the depilation treatment selectively. After the melanin absorbs Near infrared light energy, the temperature rises, in this way, the surrounding hair follicle tissues are damaged, and the hairs are removed.

V. INTENDED USE

The LED 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 LED Therapy Device (LM-LNIRA, LM-LNIRB) is substantially equivalent to the cleared predicate device.

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

Item	Proposed Device	Predicate Device K202980 (Primary)	Predicate Device K120737	Predicate Device K181568	Remark
Device name	LED Therapy Device (Planar LED/ Planar LED mini)	Laser Therapy Device	TRIA Laser Hair Removal System (TRIA)	IPL Salon Hair Reduction System	/
Product model	LM-LNIRA, LM-LNIRB	LM-L808A	TRIA	F60001	/
K number	On pending	K202980	K120737	K181568	/
Product code	OHT	GEX	GEX	OHT	Same
Classification regulation	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same

Item	Proposed Device	Predicate Device K202980 (Primary)	Predicate Device K120737	Predicate Device K181568	Remark
Intended Use	The LED 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 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.	TRIA is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. TRIA is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime. Permanent hair reduction is defined as long term, stable reduction in the number of hairs regrowing when measured out toG6, 9, and 12 months after the completion of the treatment regimen.	The IPL Salon Hair Reduction System (Model: F60001) is an over the Counter device intended for the removal of unwanted body and/or facial hair in adults. It is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs re-growing when measured at 6. 9. and 12 months after the completion of a treatment regimen.	Same
Prescription use or not	Prescription use	Prescription use	Over-The-Counter Use	Over-The-Counter Use	Same
Configuration	Main Unit	Main Unit	Main Unit	Main Unit	Same
	Hand piece	Handpiece	/	Finger switch	Same

Item	Proposed Device	Predicate Device K202980 (Primary)	Predicate Device K120737	Predicate Device K181568	Remark
	Foot Control	Foot Control	/	/	Same
Laser Type	Diode LED	Diode laser	Diode laser	Xenon Arc Flashlamp	Discussion 1
Laser Classification	Risk Group 3	Class IV	Class IV	Exempt group	Discussion 1
Laser Wavelength	780-850 nm	808 nm	800nm +/-20% (640nm-960nm)	475nm~1200nm	Discussion 1
Spot size	(17mm*22mm) 3.74cm^2 (LM-LNIRA) (17mm*17mm) 2.89cm^2 (LM-LNIRB)	(12mm*12mm) 1.44cm^2	Φ 10mm (Round)	Treatment Area (regular window): 3.025 [cm^2] Treatment area (facial adapter): 1.72 [cm^2]	Discussion 2
Fluence	1-100J/cm^2	1-100J/cm^2	6J/cm^2, 10J/cm^2, 14J/cm^2, 18J/cm^2, 22J/cm^2	Level 1: 8.62J Level 2: 9.45J Level 3: 10.64J Level 4: 11.48J Level 5: 12.70J	Same
Frequency	1-10Hz	1-10Hz	/	/	Same
Pulse Duration	3-400ms	5-400ms	/	11-12ms	Similar

Item	Proposed Device	Predicate Device K202980 (Primary)	Predicate Device K120737	Predicate Device K181568	Remark
Power Supply	AC 220~240V 50/60 Hz or AC 100~120V 50/60 Hz	AC 220~240V 50/60 Hz or AC 100~120V 50/60 Hz	100~240V,50/60Hz	100-240 VAC, 50/60Hz	Discussion 3
Dimension	430mm x 500mm x 870mm (LM-LNIRA) 408mm x 460mm x 593mm (LM-LNIRB)	650mm x 430mm x 315mm	/	143*69.5*43mm(H*W*D)	Discussion 3
Weight	30kg (LM-LNIRA) 24kg (LM-LNIRB)	22kg	/	650g	Discussion 3

Discussion 1

The proposed device is different in Laser Type, Laser Classification, Laser Wavelength, and Laser Safety test standard from the predicate device. Mainly because of these differences caused by the inconsistency of Laser Type, this difference can be proved by non-clinical test There is no security impact. The difference that mainly affects performance may exist in the Laser Wavelength. The difference in Laser Wavelength can be verified by the Predicate device (K120737), Predicate device (K181568) and the wavelength range of light absorbed by melanin to prove that there is no effect on performance. Therefore, this difference will not affect the substantial equivalency.

Discussion 2

The proposed device is different in Spot Size from the predicate, Spot size only affects the area of treatment, not affecting the therapeutic effect, Therefore, this difference will not affect the substantial equivalency.

Discussion 3

The proposed device is different in dimension and weight from the predicate device. By complying with ANSI/AAMI ES60601-1, the Electrical Safety of the proposed device is determined to be accepted, therefore, this difference will not affect the substantial equivalency.

Item	Proposed Device	Predicate Device K202980 (Primary)	Predicate Device K120737	Predicate Device K181568	Remark
Patient Contact Materials	Sapphire in handpiece	Sapphire in handpiece	/	/	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
Electrical Safety	Comply with ANSI/AAMI ES60601-1	Comply with ANSI/AAMI ES60601-1	Comply with IEC 60601-1.	Comply with IEC 60601-1.	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Laser Safety	Comply with IEC 60601-2-57, IEC 62471	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-57, IEC 62471	Similar

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 60601-2-57:2011, Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.

IEC 62471:2006, Photobiological safety of lamps and lamp systems.

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.

VIII. CLINICAL TEST CONCLUSION

No clinical study is included in this submission.

IX. SUBSTANTIALLY EQUIVALENT (SE) CONCLUSION

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.