September 11, 2023

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

Re: K230362
Trade/Device Name: Planar LED mate
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: February 9, 2023
Received: February 10, 2023

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,

Tanisha L. Hithe -S
Tanisha L. Hithe -S
2023.09.11
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Tanisha Hithe, MS, MHS
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)*
K230362

Device Name
Planar LED mate

Indications for Use *(Describe)*
The Planar LED mate is a prescription-use only device intended for removal of unwanted body and/or facial hair.

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

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

Longgang Dist., Shenzhen, China

Contact Person: Cheng Qiang

Position: Regulatory Affairs Manager

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
Secondary Contact Person:	Vini Zeng Regulatory Affairs Specialist Shenzhen Leaflife Technology Co., Ltd Tel: 086-0755-27216609 Fax: 086-0755-27215592 Email: zengvini@gmial.com
Date Prepared:	06/09/2023

II. PROPOSED DEVICE

Trade Name:	Planar LED mate
Model(s):	LH-LNIRS
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 (Primary)	
510(k) Number:	K142845
Device Name:	SILKPRO Laser Hair Removal System
Manufacturer:	Wuhan Lotuxs Technology Company, Ltd.
Predicate device (1#)	
510(k) Number:	K222316
Device Name:	IPL Hair Removal Device
Manufacturer:	Shenzhen Goodwind Technology Development CO., LTD
Predicate device (2#)	
510(k) Number:	K220103
Device Name:	LED Therapy Device
Manufacturer:	Shenzhen Leaflife Technology Co., Ltd

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

IV. DEVICE DESCRIPTION

The Planar LED mate is a prescription-use only device intended for removal of unwanted body and/or facial hair. It utilizes a diode LED as a light source (780-850 nm). It works below the skin's surface and does not involve any cutting or pulling, reducing hair growth with minimal pain. The device is only powered by the external power adapter and its emission activation is by finger switch.

The device contains a capacitive sensor to detect appropriate skin contact. If the device is not properly applied to the treatment area (in full contact with the skin), the device cannot emit the treatment light. The device is for single-person use only.

The proposed Planar LED mate 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.

The device has 5 level Output Intensity.

V. INTENDED USE

The Planar LED mate is a prescription-use only device intended for removal of unwanted body and/or facial hair.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Planar LED mate (LH-LNIRS) emits light energy to reduce hair growth, although compared to the predicate devices there may be differences in wavelengths, pulse durations, treatment spot sizes, and energy intensities. Please refer to the following table for details:

Item	Proposed Device	Predicate Device K142845 (Primary)	Predicate Device (1#) K222316	Predicate Device (2#) K220103	Remark
Device name	Planar LED mate	SILKPRO	IPL Hair Removal Device	LED Therapy Device	/
Product model	LH-LNIRS	/	ZHFIPL-II, ZHF-IPL-III	LM-LNIRA, LM-LNIRB	/
K number	K230362	K142845	K222316	K220103	/
Product code	GEX	OHT	OHT	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 K142845 (Primary)	Predicate Device (1#) K222316	Predicate Device (2#) K220103	Remark
Intended Use	The Planar LED mate is a prescription-use only device intended for removal of unwanted body and/or facial hair.	SILKPRO is an over-the counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. SILKPRO is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime.	The IPL Hair Removal Device is an over-the-counter device intended for removal of unwanted body hair.	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.	Same
Prescription use or not	Prescription use	Over-The-Counter Use	Over-The-Counter Use	Prescription use	Same
Pulsing control	Finger switch	Finger switch	Finger switch	Finger switch	Same
Light Type	Diode LED	Diode laser	IPL	Diode LED	Similar
Light Wavelength	780-850 nm	810 nm	510-1100nm	780-850 nm	Similar

Item	Proposed Device	Predicate Device K142845 (Primary)	Predicate Device (1#) K222316	Predicate Device (2#) K220103	Remark
Spot size	8mm×8mm	9mm×9mm	ZHF-IPL-II: 3.6cm² ZHF-IPL-III: 4.1cm²	(17mm*22mm) 3.74cm² (LM-LNIRA)	Similar
Output Intensity	9.5-25J/cm²	5J/cm², 10J/cm², 15J/cm², 20J/cm², 25J/cm²	ZHF-IPL-II: 2.6~4.4J/cm² ZHF-IPL-III: 2.4~3.7J/cm²	1-100J/cm²	Similar
Pulse Duration	108-320ms	/	7.2~10.8ms	3-400ms	Similar
Power Supply	AC 100-240V~ 50/60 Hz	AC 100~240V 50/60 Hz	/	AC 220~240V 50/60 Hz or AC 100~120V 50/60 Hz	Similar

Discussion

The Planar LED mate (LH-LNIRS) device, the K142845, and the K222316, devices are handheld devices, while the K220103 is a larger console device. The handheld designs allow them to be more easily transported and stored by users who can administer their own hair removal treatments. The wavelength range, pulse durations, and output intensities, of the Planar LED mate (LH-LNIRS) device are similar to those the K142845 and K222316 devices, although difference may lead to some differences in the results seen with over-the-counter devices such as K142845 (diode laser) and K221316 (IPL). The wavelength range characteristics of the Planar LED mate (LH-LNIRS) are considered to be essentially the same as the K220103 device, and while the maximum output intensity and maximum pulse duration are less, the Planar LED mate (LH-LNIRS) device's output characteristics are considered to be acceptable for this prescription-use only device for the intended use of hair removal.

Item	Proposed Device	Predicate Device K142845 (Primary)	Predicate Device (1#) K222316	Predicate Device (2#) K220103	Remark
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	No Cytotoxicity	/	Same
Sensitization	No evidence of sensitization	No evidence of sensitization	No evidence of sensitization	/	Same
Irritation	No evidence of irritation	No evidence of irritation	No evidence of irritation	/	Same
Electrical Safety	Comply with ANSI/AAMI ES60601-1, IEC 60601-1-11	Comply with ANSI/AAMI ES60601-1	Comply with ANSI/AAMI ES60601-1, IEC 60601-1-11	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 60601-2-83, IEC 62471	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-83, IEC 62471	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 devices. 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 60601-2-83, 2019 Medical electrical equipment - Part 2-83: Requirements for the basic safety and essential performance of home light therapy equipment.

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 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.

Usability and label comprehension study.

VIII. CLINICAL TEST CONCLUSION

No clinical study is included in this submission.

IX. CONCLUSIONS

The Planar LED mate (LH-LNIRS) device and predicate devices emit pulsed light to reduce hair growth, and the information provided in this premarket notification supports that the device is substantially equivalent and that it can be used safely and effectively as a prescription-use only device intended for removal of unwanted body and/or facial hair.