November 19, 2021

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

Re: K212697
Trade/Device Name: Leaf Smooth
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: August 18, 2021
Received: August 25, 2021

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 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
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)*
K212697

Device Name
Leaf Smooth

Indications for Use *(Describe)*
The Leaf Smooth is an over-the-counter 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, RP China

Phone: 086-(0)17875910506

Fax: 086-0755-27215592

Primary Contact Person: Cheng Qiang

Regulatory registration supervisor

Shenzhen Leaflife Technology Co., Ltd

Phone: 086-(0)17875910506

Tel: 086-0755-27216609

Fax: 086-0755-27215592

Email: cq@leaflife.com

Date Prepared: 08/20/2021

II. PROPOSED DEVICE

Trade Name:	Leaf Smooth
Model(s):	LH-LIPLB
Common Name:	Light Based Over-The-Counter Hair Removal
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Number:	21 CFR 878.4810
Regulation Class:	II
Product Code:	OHT
Review Panel:	General & Plastic Surgery

III. PREDICATE DEVICE

Predicate device 1#	IPL Home Use Hair Removal Device, Model D-1128: K192432
Predicate device 2#	IPL Salon Hair Reduction System, Model F60001: K181568
Predicate device 3#	iPulse SmoothSkin Gold Hair Removal System, K160968

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

IV. DEVICE DESCRIPTION

The Leaf Smooth (LH-LIPLB) is a personal, light-based, hair reduction device intended to be sold over-the-counter directly to the end user. The device provides hair reduction using Intense Pulsed Light (IPL) technology. 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 IPL emission activation is by finger switch.

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

The Leaf Smooth has 6 levels output intensity.

V. INTENDED USE

The Leaf Smooth is an over-the-counter device intended for removal of unwanted body and/or facial hair.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Leaf Smooth (LH-LIPLB) has same intended use as the predicate devices. Technological characteristics such as fluence, laser wavelength, spot size, and pulse duration, of the Leaf Smooth device are similar to those of the predicate devices.

Item	Proposed Device	Predicate Device K192432(Primary)	Predicate Device K181568	Predicate Device K160968	Remark
Device name	Leaf Smooth (LH-LIPLB)	IPL Home Use Hair Removal Device	IPL Salon Hair Reduction System	iPulse SmoothSkin Gold	/
K number	On pending	K192432	K181568	K160968	/
Product code	OHT	OHT	OHT	OHT	Same
Classification regulation	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Indications for Use	The Leaf Smooth is an over-the-counter device intended for removal of unwanted body and/or facial hair.	IPL Home Use Hair Removal Device is an over-the-counter device intended for removal of unwanted body and/or facial hair	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.	The iPulse SmoothSkin Gold Hair Removal System is indicated for the removal of unwanted hair. The iPulse Smoothskin Gold is also indicated for the permanent reduction in hair regrowth, 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	OTC	OTC	OTC	OTC	Same

Item	Proposed Device	Predicate Device K192432(Primary)	Predicate Device K181568	Predicate Device K160968	Remark
Pulsing control	Finger switch	Finger switch	Finger switch	Finger switch	Same
Delivery device	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue	Same
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Same
Wavelength range	475-1100 nm	510-1100nm	475-1200nm	510-1100nm	Similar
Spot size	3.8 cm^2	4.5 cm^2, 2.0 cm^2, 3.0 cm^2	3.02 cm^2 1.72 cm^2	3 cm^2	Similar
Fluence	4-6 J/cm^2	2.0-4.0 J/cm^2, 2.5-4.5 J/cm^2	Max 5 J/cm^2	3-6 J/cm^2	Similar
Pulse Duration	2-10ms	7.5-14ms	11-12ms	2-10ms	Similar

Item	Proposed Device	Predicate Device K192432	Predicate Device K181568	Predicate Device K160968	Remark
	Biocompatibility				
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Sensitization	No evidence of 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	No evidence of irritation	Same
	EMC, Electrical and Laser Safety				
Electrical Safety	Comply with ANSI/AAMI ES60601-1, IEC 60601-1-11	Comply with IEC 60601-1, IEC 60601-1-11	Comply with IEC 60601-1, IEC 60601-1-11	Comply with IEC 60601-1, IEC 60601-1-11	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
Light Safety	Comply with IEC 60601-2-57, IEC 62471	Comply with IEC 60601-2-57, IEC 62471	Comply with IEC 60601-2-57, IEC 62471	Comply with IEC 60601-2-57, IEC 62471	Same

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 60601-1-11:2015, Medical electrical equipment - Part 1-11 General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

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.

Software documentation consistent with moderate level of concern was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

VIII. CLINICAL TEST CONCLUSION

No clinical study is included in this submission.

IX. SUBSTANTIALLY EQUIVALENT (SE) CONCLUSION

The Leaf Smooth device has the same intended use and similar technology to those of the predicate devices. Performance testing conducted on the Leaf Smooth device supports that the Leaf Smooth can be used safely and effectively for the indications for use stated above.

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