June 12, 2026

Sanhe LEFIS Electronics Co., Ltd.
Dandan Wang
Registered Manager
Bldg. 11 #1-101, Phase 1, Zhongnan High Tech Yanjiao Science
Technology Innovation Smart Valley Industrial Park 1
Langfang, Hebei 065201
China

Re: K261204
Trade/Device Name: Intense Pulsed Light 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: ONF
Dated: March 18, 2026
Received: April 13, 2026

Dear Dandan Wang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Digitally signed by TANISHA L. HITHE -S
Date: 2026.06.12 15:24:41 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261204

Device Name
Intense Pulsed Light Therapy Device

Indications for Use *(Describe)*
It is indicated for permanent hair reduction, treatment of pigmented lesions, moderate inflammatory acne vulgaris, ephelides and vascular lesions.

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.

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510(k) Summary K261204

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

1. Date of Submission: 2026/3/18

2. Sponsor Identification

Sanhe LEFIS Electronics Co., Ltd.

Building 11 #1-101, Phase 1, Zhongnan High tech· Yanjiao Science and Technology Innovation Smart Valley Industrial Park 1, South Side of Liushan Street and West Side of Gushan West Road, Yanjiao High tech Zone, Sanhe City, 065201 Langfang City, Hebei Province, China

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3. Designated Submission Correspondent

Ms. Dandan Wang
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4. Identification of Proposed Device

Trade Name: Intense Pulsed Light Therapy Device

Classification Name: Powered Light Based Non-Light Surgical Instrument With Thermal Effect

Regulatory Information
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Classification: II
Product Code: ONF
Regulation Number: 21CFR 878.4810
Review Panel: General & Plastic Surgery

5. Indication For Use Statement:

It is indicated for permanent hairreduction, treatment of pigmented lesions, moderpate inflammatory acne vulgaris,ephelides and vascular lesions.

6. Environment of Use

healthcare facility/hospital

7. Device Description

The working principle of Intense Pulsed Light Therapy Device (IPL) is that the trigger applies a high voltage to a specific substance in the light source to trigger its ionization. After the energy storage capacitor is charged for a relatively long time, it discharges in an extremely short time, causing the avalanche ionization of the specific substance in the light source. This specific substance converts and releases the charged electrical energy in the form of high-intensity light radiation, and this discharging process is a light pulse. A filter can be used to remove the undesired emission spectrum, forming a multi-band light output to achieve different intended purposes.The device comprises a main unit, handpiece, filter, and footswitch.

8. Materials

Components	Material	Category	ContactLevel	ContactDuration
Treatment Head	Crystal（Sapphire）	Surface device	Intact skin	Short-term (<24h)
Lens hood	chrome-plated copper	Surface device	Intact skin	Short-term (<24h)

The treatment hand piece used in the system has passed the Biocompatibility test. For details, please refer to "Biocompatibility Discussion".

9. Identification of Predicate Device(s)

510(k) Number: K122995
Product Name: Intense Pulsed Light (IPL) Systems

Manufacturer: Beijing KES Biology Technology Co., Ltd.

Reference Device : K200746
Product Name: IPL Treatment Systems
Manufacturer: Shanghai Apolo Medical Technology Co., Ltd.

10. 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, ES60601-1:2005/AMD1:2012, ES60601-1:2005/AMD2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09, 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 Edition 1.0 2011-01 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.

The body-contacting components of this device are the treatment head. The biocompatibility evaluation for Intense Pulsed Light Therapy Device was conducted in accordance with the FDA guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process'". The treatment head is considered skin and subcutaneous tissue contacting for a duration of less than 24 hours. The biocompatible testing included In Vitro Cytotoxicity, Skin Sensitization and Intracutaneous Reactivity was conducted in compliance with:

- ISO 10993-5: 2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993- 10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization.
- ISO 10993-23:2021 Biological evaluation of medical devices — Part 23: Tests for irritation.

We have also conducted:

- Software verification and validation test according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices". The software for this device was considered as a Basic Documentation level. Software validation demonstrated that the software functions as specified in the software requirement specifications.
- Bench performance testing to show that the device delivers set energy parameters within specifications.

Sterilization and Shelf-Life

The proposed device is not provided sterile and does not need to be sterilized. The handpiece and the body are cleaned with a soft cloth moistened with isopropyl alcohol or ethanol of 75% strength or higher. The proposed device is reusable and does not have a restricted shelf-life.

11. Technological characteristics and substantial equivalence:

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device	Reference Device 1	Remark
Device Name	Intense Pulsed Light Therapy Device	Intense Pulsed Light (IPL) Systems	IPL Treatment Systems	/
Manufacturer	Sanhe LEFIS Electronics Co., Ltd.	Beijing KES Biology Technology Co., Ltd.	Shanghai Apolo Medical Technology Co., Ltd.	/
Product Code	ONF	ONF	ONF	Same
Class	Class II	Class II	Class II	Same
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same

Intended Use	It is indicated for permanent hairreduction, treatment of pigmented lesions, moderate inflammatory acne vulgaris,ephelides and vascular lesions.	The Intense Pulsed Light (IPL) Systems (inclusive of the handpiece used to deliver pulsed-light energy) are indicated for use in surgical, aesthetic and cosmetic applications in permanent hair reduction, treatment of pigmented lesions, moderate inflammatory acne vulgaris. ephelides (freckles), and vascular lesions.	The IPL treatment system is intended for medical use in the treatment of the following dermatologic conditions: - Permanent hair reduction- long-term stable reduction in number of hairs re-growing after a treatment regimen; - Moderate inflammatory acne vulgaris; - Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles); - Cutaneous lesions including scars; - Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial truncal and leg telangiectasias, erythema of rosacea, leg veins, spider angiomas and venous malformations.	Analysis 1
Indication for use	Prescription Use	Prescription Use	Prescription Use	Same

Table 2 Performance Comparison

ITEM	ProposedDevice	PredicateDevice	ReferenceDevice1	Remark
Light source	Intense pulsed light	Intense pulsed light	Intense pulsed light	Same
Wavelength	420nm-1200nm、515nm-1200nm、560nm-1200nm、590nm-1200nm、640nm-1200nm、695nm-1200nm	430-1200nm、 530-1200nm、 640-1200nm Optional： 480-1200nm、 560-1200nm、 590-1200nm、 690-1200nm、 750-1200nm	420 – 1200 nm	Analysis 1
Deliver system	Sapphire	Sapphire	Sapphire	Same
Energy output	4J/cm2- 32J/cm2	I 0-60J/cm'	4.1-50.8 J/cm2	Analysis 2
Pulse sequence	2 to 10.	1-15 pulses	/	Analysis 2
Pulse width	0.5ms/1ms	l-20ms	5-20 ms	Analysis 3
Pulse delay	5ms to 50ms	5-50ms	5-50 ms	Same
Spot Size	30X12mm.	MED-210：15mm×50mm；（optional） 12mm×33mm、15mm×35mm MED-230： A ：12mm×33mm B ：15mm×50mm（optional）15mm×35mm	12*35mm, 15*50mm	Analysis 4
Filters	420nm-1200nm/560nm-1200nm：Acne vulgaris； 515nm-1200nm/560nm-1200nm：Pigmented lesions； 515nm-1200nm/560nm-1200nmEphelides； 560nm-1200nm/590nm-1200nm：vascular lesions； 640nm-1200nm/695nm-1200nm：Hair removal;	moderate inflammatory acne vulgaris： 430-1200/480-1200/530-1200 pigmented lesions：480-1200/530-1200/560-1200 ephelides (freckles)：480-1200/530-1200 vascular lesions：530-1200/560-1200/590-1200，	420 -1200nm: Acne; 510 -1200nm: Acne, vascular, pigment; 560 -1200nm: Acne, vascular, pigment;	Same

ITEM	ProposedDevice	PredicateDevice	ReferenceDevice1	Remark
		permanent hair reduction：640-1200/690-1200/ 750-1200	610-1200nm: Hair removal; 640-1200nm: Hair removal; 690-1200nm: Hair removal;	
Fluences	420nm-1200nm：4- 32J/cm2 515nm-1200nm：4- 32J/cm2 560nm-1200nm：4- 30J/cm2 590nm-1200nm：4- 28J/cm2 640nm-1200nm：4-26J/cm2 695nm-1200nm：4-20J/cm2	430-1200/480-1200/530-1200 ： 10-40 J/cm2 480-1200/530-1200/560-1200 ： 12-44 J/cm2 530-1200/560-1200/590-1200：10-42J/cm2 640-1200/690-1200/ 750-1200 ： 10-44 J/cm2	420 -1200nm: 4.1-50.8J/cm2; 510 -1200nm: 3.8-47 J/cm2; 560 -1200nm: 3.7-43.3 J/cm2; 610-1200nm: 3.5-38.7 J/cm2; 640-1200nm: 3.3-37.4J/cm2; 690-1200nm: 3.1-33.4J/cm2;	Analysis 2
Deliver materials	Direct sapphire Coupling	/	Direct sapphire Coupling	Same
Cooling method	Water cooling, forced-air cooling, copper and TEC	/	HS-650K&HS-660K: Water cooling, forced-air cooling, copper and TEC; HS620K, HS-300CK&HS-310K: Water cooling and forced-air cooling,	Same
Power Supply	110V 60Hz or230V 50/60Hz	220V±20V 50Hz or I I0V±20V 60Hz	/	Similar
Max. power consumption	3300VA	MED-210：1400 W MED-230：2000 W	/	Analysis 5

Table 3 Safety Comparison

ITEM	ProposedDevice	PredicateDevice	ReferenceDevice	Remark
Biocompatibility	Passed the test as per ISO 10993-5，ISO 10993-10, ISO10993-23	/	Passed the test as per ISO 10993-1	Same
Patient Contact Sites	Skin	Skin	Skin	Same
Electrical Safety	Comply with IEC 60601-1	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	Same
Safety	Comply with IEC 60601-2-57	/	Comply with IEC 60601-2-57	Same

Analysis 1 Wavelength

The wavelength difference between the proposed device and the predicate device is only minor deviations in the starting wavelength, while the end wavelength (1200nm) is completely consistent. The characteristic absorption spectra of the core target tissues (pigment, blood vessels, hair follicles) are fully covered, and the device complies with relevant standards. This difference does not alter the treatment principle or performance, and thus does not affect the safety and effectiveness of the product.

Analysis 2 Energy output & Pulse sequence

The differences in energy output and pulse sequence are both differences in the breadth of parameter ranges. The effective parameter ranges required for core treatment completely overlap, and they comply with relevant standards, so they do not affect the safety and effectiveness of the product.

Analysis 3 Pulse width

The pulse width of the test device is set to 0.5ms/1ms, while the predicate device adopts a pulse width range of 1-20ms. The 1ms mode of the test device is fully covered within the validated safety range of the predicate device. The newly added 0.5ms mode, which is narrower than the predicate’s minimum 1ms pulse width, is controlled under the safety boundary of the peak power and total energy verified by the predicate device through the hardware power limiting design, with no higher energy density or

thermal effect introduced. The key safety parameter, pulse duration (5-50ms), remains identical between the two devices, ensuring no change in the upper limit of total energy output. This difference is a controlled contraction and low-risk adjustment of the validated safety range of the predicate device, and will not adversely affect the safety of the device.

Analysis 4 Spot Siz

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

Analysis 5 Max. power consumption

There is a difference in Max. Power between the proposed device and the predicate device. After verification, the proposed device complies with the requirements of AAMI/ANSI/ES60601-1 and IEC 60601-1-2. The verification results show that this difference in Max. Power will not give rise to any safety or effectiveness issues; therefore, this difference will not affect the safety and effectiveness of the proposed device.

Substantially Equivalent(SE) Conclusion

Intense Pulsed Light Treatment device has the same intended use, similar indications for use, the same technological characteristics, the same energy used, and the same operating principles as its predicates. The non-clinical data and performance testing reports in this submission demonstrate that Intense Pulsed Light Treatment device meets the expected performance requirements. Any difference between the subject and predicate device do not raise new issues of safety or effectiveness. Based on above analysis, Intense Pulsed Light Treatment device is substantial equivalent to the cited predicate device.

12. Clinical Test Conclusion

    No clinical study is included in this submission.

13. Substantially Equivalent(SE) Conclusion

    Intense Pulsed Light Therapy Device has the same intended use, similar indications for use, the same technological characteristics, the same energy used, and the same operating principles as its predicates. The non-clinical data and performance testing reports in this submission demonstrate that Intense Pulsed Light Therapy Device meets the expected performance requirements. Any difference between the subject and predicate device do not raise new issues of safety or

effectiveness. Based on above analysis, Intense Pulsed Light Therapy Device is substantial equivalent to the cited predicate device.