November 14, 2024

Nanjing Bestview Laser S&T Co., Ltd.
Jing Wang
Management Representative
1st & 2nd Floor, Building 5, Area 1, Phase 2
Liandong U Valley Science and Technology Innovation Park
Nanjing, Jiangsu 210000
China

Re: K242440
Trade/Device Name: Intense Pulsed Light Treatment System (LK-PT)
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: August 16, 2024
Received: August 16, 2024

Dear Jing 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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

Yan Fu -S Digitally signed by Yan Fu -S
Date: 2024.11.14 22:52:51 -05'00'

for Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242440

Device Name

Intense Pulsed Light Treatment System (LK-PT)

Indications for Use *(Describe)*

The Intense Pulsed Light Treatment System (Model: LK-PT) is indicated for use in surgical and aesthetic applications in permanent hair removal, reduction of benign pigmented lesions and benign vascular lesions.
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 regimen.

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 K242440

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K242440

1. Date of preparation

August 16, 2024

2. Sponsor

Name: Nanjing Bestview Laser S&T Co., Ltd.

Address: 1st&2nd Floor, Building5, Area1, Phase2, Liandong U Valley Science and Technology Innovation Park, No.1 Hengyi Road, Nanjing Economic and Technological Development Zone, Nanjing 210000, Jiangsu, P.R. China

Contact Person: Jing Wang

Position: Management Representative

Phone: +86-15824831075

E-mail: jingwang@bestviewlaser.com

3. Identification of predicate device

510(k) Number: K192521

Trade Name: Intense Pulsed Light Treatment System

Product Code: ONF

Manufacturer: Shangdong Huamei Technology Co., Ltd.

4. Identification of proposed device

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

Trade name: Intense Pulsed Light Treatment System

Model: LK-PT.

Regulatory Information:

Classification: Class II

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

Regulation: 21CFR 878.4810

Review Panel: General & Plastic Surgery

Product Code: ONF

5.Device Description:

The LK-PT device is an intense pulsed light system which delivers intense pulsed light at wavelengths ranging from 560nm ~ 1200nm. Intense Pulsed Light(IPL) system work on the principles of selective thermolysis. That is, causing thermal damage to target chromophores by using light of appropriate wavelength in pulses that exceeds the chromophores' thermal relaxation time but sparing normal skin by limiting the pulse width below the thermal relaxation time for skin.

IPL systems are different from lasers in that they deliver many wavelengths in each pulse of light instead of just one wavelength. Generally, IPL enhances penetration without using excessive energy levels and enables targeting of specific chromophores.

6.Indications for Use

The Intense Pulsed Light Treatment System (Model: LK-PT) is indicated for use in surgical and aesthetic applications in permanent hair removal, reduction of benign pigmented lesions and benign vascular lesions.

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 regimen.

7. Substantially Equivalent (SE) Comparison

Item	Proposed Device	Predicate Devices	Remark
Trade Name	Intense Pulsed Light Treatment System	Intense Pulsed Light Treatment System	/
Model	LK-PT	HM-IPL-B8	/
510(k) Number	/	K192521	/
Product Code	ONF	ONF	Same
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	Same
Class	II	II	Same
Intended Use	The Intense Pulsed Light Treatment System (Model: LK-PT) are indicated for use in surgical and aesthetic applications in permanent hair removal, reduction of benign	The Intense Pulsed Light Treatment System (Model: HM-IPL-B8) are indicated for use in surgical and aesthetic applications in permanent hair	Same

	pigmented lesions and benign vascular lesions. 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 regimen.	removal, reduction of benign pigmented lesions and benign vascular lesions. 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 regimen.	
Where Used	Hospital	Hospital	Same
Light source	Intense pulsed light	Intense pulsed light	Same
Wavelength	560-1200nm 695- 1200nm	430-1200nm, 530-1200nm, 640-1200nm, Optional:480-1200nm, 560-1200nm, 590-1200nm, 690-1200nm, 750 -1200nm	Analysis1
Deliver system	Sapphire	Sapphire	SE
Energy density	6-50 J/cm2	10-50J/cm^2	Analysis2
Pulse Delay	10-50ms	5-50ms	Analysis3
Pulse Width	2-10 ms	1-20ms	Analysis3
Spot size	8mm*40 mm	15mm×50mm; 80mm×40mm;	Analysis4
Max power	2500W	2000W	Analysis5

(1) Analysis 1: Wavelength

The wavelength range of the LK-PT device is within the wavelength range of the predicate for the indications for use, and the slight difference does not result in a negative effect on safety and effectiveness.

(2) Analysis 2: Energy density

The energy density range of the proposed device covers the energy density range of the predicate device. Although the minimum energy density is lower than the minimum energy density of the predicate device, but the maximum energy density doesn't exceed the maximum energy density of the predicate device.

(3) Analysis 3: Energy density Pulse Delay and Width

The pulse delay and the pulse width range of the proposed device is within the corresponding range of the predicate for the indications for use, and the slight difference does not result in a negative effect on safety and effectiveness.

(4) Analysis 4: Spot Size

The spot size of the proposed device is different from that of predicate device, but the difference of the spot size is only for different treatment area, and it does not negatively affect the output parameter for treatment.

(5) Analysis 5: Max power

The max power of the proposed device is different from that of predicate device, but the power of the machine refers to the rate at which the machine consumes electrical energy while running, so it will not have much impact on the performance of the machine.

Discussion

The proposed device is different in wavelength, Energy density, Pulse Delay, Pulse width and spot size from the predicate device. By complying with non-clinical test conducted, the proposed device is determined to be substantially equivalency with predicate device.

8. Biocompatibility

The Intense Pulsed Light Treatment System (Model: LK-PT) have been evaluated in accordance with Part 10993 of the International Standard Organization (ISO). Standard tests administered include:

- 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.
- 10993-23: 2021, Biological Evaluation of Medical Devices - Part 23: Tests for irritation.

9.Summary of non-clinical performance Tests

- ANSI AAMI ES60601-1: 2005&A1:2012 &A2:2021: Medical Electrical Equipment - Part 1: General Requirement for Basic Safety and Essential Performance;
- IEC 60601-1-2: 2014+A1:2020, Medical Electrical Equipment - Part 1-2: General Requirement 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, cosmetic and aesthetic use;

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

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. 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.