August 9, 2023

Smedtrum Medical Technology Co., Ltd.
Crimson Wu
Senior Regulatory Engineer
1F., No. 8, Ln. 97, Wugong Rd.,
New Taipei City, Xinzhuang Dist. 248016
Taiwan

Re: K231394
Trade/Device Name: Intense Pulsed Light System
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: May 12, 2023
Received: May 15, 2023

Dear Crimson Wu:

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,

Jianting Wang -S

Jianting Wang
Acting 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)*
K231394

Device Name
Intense Pulsed Light System

Indications for Use *(Describe)*
The Intense Pulsed Light System is intended for medical use in the treatment of the following conditions:
1. Moderate inflammatory acne vulgaris;
2. Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles);
3. Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial truncal and leg telangiectasias, erythema of rosacea, leg veins, spider angiomas and venous malformations;
4. Permanent hair reduction-long-term stable reduction in number of hairs re-growing after 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.

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Section 5 : 510(k) Summary
Intense Pulsed Light System

I. SUBMITTER

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Date of preparation: May 12th, 2023

II. DEVICE

Trade Name:	Intense Pulsed Light System
Common or Usual Name:	Intense Pulsed Light System
Product code:	ONF
Classification Name:	Powered Light Based Non-Light Surgical Instrument With Thermal Effect 21 C.F.R. § 878.4810, Device Class II

III. PREDICATE DEVICE

Manufacturer	Shanghai Apolo Medical Technology Co., Ltd.
Trade Name:	IPL Treatment Systems
Common or Usual Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name:	Powered Light Based Non-Light Surgical Instrument With Thermal Effect 21 C.F.R. § 878.4810, Device Class II
Premarket Notification:	K200746　May 15th, 2020

IV. DEVICE DESCRIPTION

Intense Pulsed light (IPL) System is a type of intensive, broadband, coherent light source which has a wavelength spectrum of 420 nm -1200 nm. There are six optical filters that can be using in this system listed in table. With these special properties, the IPL System has a wide application in non-ablative therapies based on theory of human

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skin tissue's selective absorption.

Spectra	Application areas	Expected Working Life
420 -1200nm	Vascular, acne, pigmentation	100,000 shots
510 -1200nm	Vascular, pigmentation	80,000 shots
560 -1200nm	Vascular, pigmentation	70,000 shots
610 -1200nm	Hair removal	60,000 shots
640 -1200nm	Hair removal	50,000 shots
610 – 980nm (SHR)	Hair removal	30,000 shots

V. INDICATIONS FOR USE

The Intense Pulsed Light System is intended for medical use in the treatment of the following conditions:

1. Moderate inflammatory acne vulgaris;

2. Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles);

3. Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial truncal and leg telangiectasias, erythema of rosacea, leg veins, spider angiomas and venous malformations;

4. Permanent hair reduction-long-term stable reduction in number of hairs re-growing after a treatment regimen.

COMPARISON OF TECHNOLOGICAL CHARATERISTICS WITH THE PREDICATE DEVICE

Feature	**Proposed device**	**Predicate device (K200746)**
Device Name	Intense Pulsed Light System	IPL Treatment Systems
Product Code	ONF	ONF
Regulation No.	21 CFR 878.4810	21 CFR 878.4810
Device Class	Class II	Class II

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Feature	**Proposed device**	**Predicate device (K200746)**
Indication for Use	The Intense Pulsed Light System is intended for medical use in the treatment of the following conditions: 1. Moderate inflammatory acne vulgaris; 2. Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles); 3. Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial truncal and leg telangiectasias, erythema of rosacea, leg veins, spider angiomas and venous malformations; 4. Permanent hair reduction- long-term stable reduction in number of hairs re-growing after a treatment regimen.	The IPL treatment systems 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.
Light Source	Intense Pulsed light (Xenon Flash Lamp)	Intense Pulsed light (Xenon Flash Lamp)
Wavelength	420 – 1200 nm	420 – 1200 nm
Light Delivery System	Handpiece	Handpiece
Filter	420 -1200nm: Acne; 510 -1200nm: Acne, vascular, pigment; 560 -1200nm: Vascular, pigment; 610-1200nm: Hair removal; 640-1200nm: Hair removal; 610-980nm: Hair removal;	420 -1200nm: Acne; 510 -1200nm: Acne, vascular, pigment; 560 -1200nm: Acne, vascular, pigment; 610-1200nm: Hair removal; 640-1200nm: Hair removal; 690-1200nm: Hair removal;

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Feature	**Proposed device**	**Predicate device (K200746)**
Fluence	420 -1200nm: 4.1-34.8 J/cm^2; 510 -1200nm: 3.8-31.6 J/cm^2; 560 -1200nm: 3.9-30.2 J/cm^2; 610-1200nm: 3.9-27.8 J/cm^2; 640-1200nm: 3.3-24.9 J/cm^2; 610-980nm: 3.2-23.3 J/cm^2;	420 -1200nm: 4.1-50.8 J/cm^2; 510 -1200nm: 3.8-47 J/cm^2 560 -1200nm: 3.7-43.3 J/cm^2 610-1200nm: 3.5-38.7 J/cm^2 640-1200nm: 3.3-37.4 J/cm^2 690-1200nm: 3.1-33.4 J/cm^2
Pulsed Energy density	4.1~35 J/cm^2 (10~50 Level)	4.1-50.8 J/cm^2
Pulsed width	5~20 ms	5~20 ms
Pulsed duration	5~50 ms	5~50 ms
Spot Size	12 mm × 35 mm & 15 mm × 50 mm	12 mm × 35 mm & 15 mm × 50 mm
Cooling	water + air + TEC	water + air + TEC

VI. PERFORMANCE DATA

The Intense Pulsed Light System has been determined through engineering testing to verify optical energy output and electrical safety.

Electrical safety and electromagnetic compatibility

The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1: 2005+corr.1:2006+Corr.2.2007+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2020 Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems

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

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance

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for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern since a failure of the software could result in minor injury to a patient or to a user of the device.

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 ethanol of 70% strength or higher. The proposed device is reusable and does not have a restricted shelf-life.

Biocompatibility

The handpiece sapphire tip may be contact with the intact skin of patients. According to FDA guidance document "Use of International Standard ISO 10993-1, " Biological evaluation of medical device – Part 1: Evaluation and testing within a risk management process "" three biological effects were determined in following three test: Cytotoxicity, Sensitization and Irritation.

In Cytotoxicity test, to determine the potential cytotoxicity of finished components, L-929 cell cultured in 96-well plates were treated with extract of 2 test article group:

Test article group 1: Test article extract, original extract

Test article group 2: 50% extract of the test article

The test results showed that the cell morphological grading of test group is the same as negative control group. The cell viability represented 100%, 93%, 11%, 74% and 96%; the mortality showed 0%, 7%, 89%, 26% and 4%. Under the conditions of this test, the extract of test article passed test requirement and did not show potential cytotoxicity to mouse fibroblast L-929 cells.

In Skin sensitization test, Guinea Pig Maximization Test (GPMT) were performed for determination of the skin sensitizing potential of test article extraction. The appearance of the challenge skin sites of the test and control animals 24 h and 48 h after removal of the patch was scored by grade of the skin reactions for erythema and oedema according to the Magnusson and Kligman grading scale. Under GPMT method, the results shows the test article did not cause delayed dermal contact sensitization in the guinea pig.

In Skin irritation test, The results showed that there were no erythema and edema findings in either the control or treatment group, and there were no mortalities. Furthermore, the PII values were 0 (Non-irritant). Therefore, a single topical

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application of 0.5 ml of the test article extracts (Polar and non-polar groups) did not cause skin irritation.

Three biological effects, cytotoxicity, sensitization and irritation testing, were performed and test results did not identify any biological response or risk. The Intense Pulsed Light System meets the ISO 10993-1 standard requirements for biocompatibility and no further characterization testing is required.

Bench testing

Intense Pulsed Light system is an Light source equipment. The spatial variation of the LS equipment output over the treatment area shall not deviate from the average irradiance or radiant exposure by more than ±20%

The product fulfills the requirements of IEC 60601-2-57.

VII. CONCLUSION

The Intense Pulsed Light System 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 System 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, the Intense Pulsed Light System is as safe, as effective, and performs as well as the cited predicate device.