August 12, 2022

Beijing Globalipl Development Co., Ltd.
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
China

Re: K220385
Trade/Device Name: Intense Pulsed Light Equipment
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: February 9, 2022
Received: February 10, 2022

Dear Ray 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 (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
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)*
K220385

Device Name
US 500 Intense Pulsed Light Equipment

Indications for Use *(Describe)*
The US 500 Intense Pulsed Light Equipment is indicated for use in surgical and aesthetic applications in permanent hair removal. Permanent hair removal 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

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.

1. Date of Preparation:2022/08/12

2. Sponsor Identification

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Intense Pulsed Light Equipment

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

Regulatory Information

Classification Name: Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Classification: II
Product Code: ONF
Regulation Number: 878.4810
Review Panel: General & Plastic Surgery

Indication For Use Statement:

The US 500 Intense Pulsed Light Equipment is indicated for use in surgical and aesthetic applications in permanent hair reduction. 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.

Device Description:

The US500 Intense Pulsed Light Equipment is a device that emits intense pulsed light in order to achieve hair reduction. The light source is a Xenon lamp that emits light which is filtered to include suitable wavelengths for hair reduction. The device is electrically powered, and main components include the console which includes electrical components and a touchscreen user interface, the IPL handpiece and cable, and a footswitch. The light pulses are emitted from the handpiece which is water cooled. The device is for prescription use only.

5. Identification of Predicate Device(s)

510(k) Number: K161286
Product Name: IPL Therapy Machine
Manufacturer: Beijing ADSS Development Co., Ltd

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device conforms to the following standards:

- IEC 60601-1:2012, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance.
- EC 60601-1-2:2014, Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-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 and cosmetic/aesthetic use
- IEC 62471:2006 Photobiological safety of lamps and lamp system
- ISO 10993-5: 2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

7. Clinical Test Conclusion

A clinical study was not considered to be needed for this 510(k).

8. Substantially Equivalent (SE) Comparison

Table 6-1 General Comparison

Item	Proposed Device	Predicate Device	Remark
Device Name	Intense Pulsed Light Equipment	IPL Therapy Machine	/
Classification Regulation	21 CFR 878.4810	21 CFR 878.4810	SAME
Classification Panel	General & Plastic Surgery	General & Plastic Surgery	SAME
Class	II	II	SAME
Product Code	ONF	ONF	SAME
Common Name	Powered Light Based Non-Laser Surgical Instrument With Thermal Effect	Powered Light Based Non-Laser Surgical Instrument With Thermal Effect	SAME
Indication for use	The US 500 Intense Pulsed Light Equipment is indicated for use in surgical and aesthetic applications in permanent hair reduction. 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.	The VE2000 device is indicated for use in surgical, aesthetic applications in permanent hair reduction, 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.	SIMILAR The subset indication for use for hair reduction is the same

Table 6-2 Performance Comparison

ITEM	Proposed Device	Predicate Device	Remark
Light source	Intense pulsed light	Intense pulsed light	SAME
Wavelength	640nm-1200nm,	480nm – 1200nm; 590nm – 1200nm; 640nm – 1200nm	SIMILAR
Deliver system	Sapphire	Sapphire	SAME
Energy density	1-40J/cm²	1-50J/cm²	SIMILAR
Pulse Width	1.0-9.9ms, adjustable	1-25ms	SIMILAR
Pulse Interval	1 – 99 ms	1 – 50 ms	SIMILAR
Light output interval	1 – 4 s	1 – 4s	SAME
Pulse Number	1 - 6	1-6	SAME
Max. Power	2200VA	2200VA	SAME
Spot size	15 x 50mm	12 x 30 mm	SIMILAR
Cooling mode	close-cycle water cooling+ air Contact cooling	Compressor closed circuit water chiller with integrated heat exchanger.	SIMILAR
Power supply	AC 110/230V 50/60Hz	110V, 50Hz	SIMILAR

9. Conclusion

The US500 Intense Pulse Light Equipment proposed device in this 510(k) uses the same IPL technology that is used in the predicate device K161286. Differences between the proposed device and predicate device do not raise new types of questions regarding safety and effectiveness, and performance testing demonstrates that the proposed device can be used safely and effectively for the proposed indications for use. The proposed US500 Intense Pulse Light Equipment device is considered to be substantially equivalent to the predicate K161286 device.