April 21, 2023

Shangdong Huamei Technology Co., Ltd.
% Ray Wang
General Manger
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, 102401
China

Re: K230816
Trade/Device Name: Intense Pulsed Light Treatment 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: March 23, 2023
Received: March 24, 2023

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 -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.

Submission Number *(if known)*

K230816

Device Name

Intense Pulsed Light Treatment System (EROSE-YA)

Indications for Use *(Describe)*

The Intense Pulsed Light Treatment System (Model: HM-IPL-B8) are 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.

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.

The assigned 510(k) Number: **K230816**

1. Date of Preparation: 03/23/2023

2. Sponsor Identification

Shangdong Huamei Technology Co., Ltd.

No. 588, Changning Street, High-tech District, WeiFang, ShanDong, China, 261205

Contact Person: Yugui Dong
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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 Treatment System
Common Name: Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Model(s): EROSE-YA

Regulatory Information:
Classification Name: Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Classification: II;
Product Code: ONF;
Regulation Number: 21 CFR 878.4810；
Review Panel: General & Plastic Surgery;

Indication For Use Statement:

The Intense Pulsed Light Treatment System (Model: EROSE-YA)) 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.

Device Description:
The EROSE-YA device is an intense pulsed light system which delivers intense pulsed light at wavelengths ranging from 430nm-1200nm. Intense Pulsed Light (IPL) systems 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.

5. Identification of Predicate Device(s)

510(k) Number
K192521

Predicate Device Name
Intense Pulsed Light Treatment System

Manufacturer
Shangdong Huamei Technology Co., Ltd.

Intended Use:

The Intense Pulsed Light Treatment System (Model: HM-IPL-B8) are 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.

6. 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:

a) IEC 60601-1-2 :2014/AMD1:2020, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.

b) IEC 60601-1:2005+A1:2012+A2:2020, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

c) IEC60601-2-57:2011, 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

d) ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity.

e) ISO 10993-10:2010 Standard, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device Intense Pulsed Light Treatment System (K192521)	Remark
Product Code	ONF	ONF	SE
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SE
Class	II	II	SE
Intended Use	The Intense Pulsed Light Treatment System (Model: HM-IPL-B8) are 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.	The Intense Pulsed Light Treatment System (Model: HM-IPL-B8) are 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.	SE

Table 2 Performance Comparison

ITEM	Proposed Device	Predicate Device Intense Pulsed Light Treatment System (K192521)	Remark
Light source	Intense pulsed light	Intense pulsed light	SE
Wavelength	430-1200nm ， 530-1200nm ， 640-1200nm Optional ： 480nm-1200nm ， 560-1200nm，590-1200nm，690-1200nm，750nm-1200nm	430-1200nm ， 530-1200nm ， 640-1200nm Optional ： 480nm-1200nm ， 560-1200nm，590-1200nm，690-1200nm，750nm-1200nm	SE
Deliver system	Sapphire	Sapphire	SE
Energy density	10-50J/cm2 ±20%error	10-50J/cm2	SE
Pulse Delay	5-50ms ±10%error	5-50ms	SE
Pulse Width	1-20ms ±10%error	1-20ms	SE
Max. Power	2000W	2000W	SE
Spot size	15mm×50mm; 80mm×40mm ±20%error	15mm×50mm; 80mm×40mm	SE

Table 3 Setting Comparison of Specified Indication for Use

ITEM	Proposed Device	Predicate Device Intense Pulsed Light Treatment System (K192521)	Remark
permanent hair reduction			
Wavelength Range (nm)	640-1200/690-1200/ 750-1200	640-1200/690-1200/ 750-1200	SE
Energy Range (J/cm2)	10-44	10-44	
Pulse Width (ms)	3-14	3-14	
Pulse Delay (ms)	16-32	16-32	
Spot Size (mm)	15mm×50mm; 80mm×40mm;	15mm×50mm; 80mm×40mm;	
pigmented lesions			
Wavelength Range (nm)	480-1200/530-1200/560-1200	480-1200/530-1200/560-1200	SE
Energy Range (J/cm2)	12-44	12-44	
Pulse Width (ms)	3-9	3-9	
Pulse Delay (ms)	16-32	16-32	
Spot Size (mm)	15mm×50mm; 80mm×40mm;	15mm×50mm; 80mm×40mm;	
vascular lesions			
Wavelength Range (nm)	530-1200/560-1200/ 590-1200	530-1200/560-1200/ 590-1200	SE
Energy Range (J/cm2)	10-42	10-42	
Pulse Width (ms)	3-8	3-8	
Pulse Delay (ms)	16-32	16-32	
Spot Size (mm)	15mm×50mm; 80mm×40mm;	15mm×50mm; 80mm×40mm;	

Table 4 Safety Comparison

ITEM	Proposed Device EROSE-YA	Predicate Device Intense Pulsed Light Treatment System (K192521)	Remark
Power supply	110V±10%　60Hz	110V±10%　60Hz	SE
Electrical Safety	The proposed devices were tested to demonstrated to comply with IEC 60601-1	The proposed devices were tested to demonstrated to comply with IEC 60601-1	SE
EMC	The proposed devices were tested to demonstrated to comply with IEC 60601-1-2	The proposed devices were tested to demonstrated to comply with IEC 60601-1-2	SE
Patient Contact Material	Handpiece (Sapphire Crystal)	Handpiece (Sapphire Crystal)	SE
Biocompatibility			
Cytotoxicity	No toxicity (ISO 10993-5)	No toxicity (ISO 10993-5)	SE
Irritation	Applied sample did not induce irritation to skin. (ISO 10993 -10)	Applied sample did not induce irritation to skin. (ISO 10993 -10)	SE
Sensitization	The test article showed no signification evidence of causing skin sensitization in the guinea pig .(ISO 10993-10)	The test article showed no signification evidence of causing skin sensitization in the guinea pig .(ISO 10993-10)	SE

9. Substantially Equivalent (SE) Conclusion

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