



December 6, 2019

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

Re: K192521

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: September 11, 2019
Received: September 13, 2019

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,

Purva Pandya
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

Indications for Use

510(k) Number (if known)
K192521

Device Name
Intense Pulsed Light Treatment System

Indications for Use (Describe)

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

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: K192521

1. Date of Preparation: 11/25/2019

2. Sponsor Identification

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3. Designated Submission Correspondent

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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): HM-IPL-B8

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: HM-IPL-B8) 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 HM-IPL-B8 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: K122995

Predicate Device Name: Intense Pulsed Light (IPL) Systems

Manufacturer: Beijing KES Biology Technology Co., Ltd.

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:

510(k) Summary

- a) IEC 60601-1-2:2014, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.
- b) IEC 60601-1:2005/A1:2012, 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 7-1 General Comparison

ITEM	Proposed Device	Predicate Device Intense Pulsed Light (IPL) Systems(K122995)	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.	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 removal, reduction of pigmented lesions, acne therapy, freckles, vascular lesions and facial blemish.	SE

Table 7-2 Performance Comparison

ITEM	Proposed Device	Predicate Device Intense Pulsed Light (IPL) Systems(K122995)	Remark
Light source	Intense pulsed light	Intense pulsed light	SE
Wavelength	430-1200nm, 530-1200nm, 640-1200nm, Optional: 480-1200nm, 560-1200nm, 590-1200nm, 690-1200nm, 750 -1200nm	430-1200nm, 530-1200nm, 640-1200nm, Optional: 480-1200nm, 560-1200nm, 590-1200nm, 690-1200nm, 750 -1200nm	SE
Deliver system	Sapphire	Sapphire	SE
Energy density	10-50J/cm ²	10-60J/cm ²	Analysis 1
Pulse Delay	5-50ms	5 - 50ms	SE
Pulse Width	1-20ms	1-20ms	SE
Max. Power	2000W	2000 W	SE
Spot size	15mm×50mm; 80mm×40mm;	MED-210: 15mmX50mm (optional: 12mmX33mm, 15mmX35mm) MED-230: A: 12mm X33mm; B: 15mmX50mm (optional: 15mmX35mm)	Analysis 2

Table 7-3 Setting Comparison of Specified Indication for Use

ITEM	Proposed Device	Predicate Device Intense Pulsed Light (IPL) Systems(K122995)	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;	12mm X33mm; 15mmX50mm 15mmX35mm	
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	

510(k) Summary

Pulse Delay (ms)	16-32	16-32	
Spot Size (mm)	15mm×50mm; 80mm×40mm;	12mm X33mm; 15mmX50mm 15mmX35mm	
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;	12mm X33mm; 15mmX50mm 15mmX35mm	

Analysis 1:

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

Therefore, the slight difference is considered to have no negative effect on effectiveness and safety.

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. Therefore, the slight difference is considered to have no negative effect on effectiveness and safety.

Table 7-4 Safety Comparison

ITEM	Proposed Device HM-IPL-B8	Predicate Device Intense Pulsed Light (IPL) Systems(K122995)	Remark
Power supply	110V $\pm$ 10% 60Hz	220V $\pm$ 20V 50Hz or 110V $\pm$ 20V 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.