May 15, 2020

Shanghai Apolo Medical Technology Co., Ltd.
Felix Li
RA Supervisor
4F, Building A, No.388, Yindu Road, Xuhui District
Shanghai, Shanghai 200231
China

Re: K200746
Trade/Device Name: IPL Treatment Systems
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 9, 2020
Received: March 23, 2020

Dear Felix Li:

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,

Colin Kejing Chen
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k200746

Device Name
IPL Treatment System

Indications for Use *(Describe)*

The IPL treatment system 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.

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 3-510(k) summary

I Submitter

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Date of preparation: Apr 28th, 2020

II Proposed Device

Trade Name of Device:	IPL Treatment Systems
Common name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Number:	21 CFR 878.4810
Regulatory Class:	Class II
Product code:	ONF
Review Panel	General & Plastic Surgery

III Predicate Devices

510(k) Number:	K093627
Trade name:	iPulseLight IPL System (HS 300C, HS 650)
Common name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification:	Class II
Product Code:	ONF
Manufacturer	Shanghai APOLO Medical Technology Co., Ltd.

IV Device description

The IPL Treatment Systems utilizes an intense, visible, broad-spectrum pulse of light that when used with interchangeable filters, allowing it to selectively heat the target

for different indications. The optical component is intended to drive the IPL energy to concentrate where the optical energy has selectively heated the target.
The Intense pulsed light (IPL) is a type of intensive, broadband, coherent light source which has a wavelength spectrum of 420 nm -1200 nm. The light-based component delivers optical energy that is absorbed by specific chromophores in the skin, which is converted to heat, according to the principle of selective photothermolysis.

The proposed device consists of the main unit, control panel and the treatment handpiece(s).

V Indication for use

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.

VI Comparison of technological characteristics with the predicate devices

Item	Proposed device	Predicate device (K093627)	Discussion
Product Code	ONF	ONF	Identical
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	Identical
Class	Class II	Class II	Identical
Indication for use	The IPL treatment systems is intended for medical use in the treatment of the following dermatologic conditions: - Permanent hair reduction- long-term	iPulseLight IPL System (HS 300C, HS 650) are identical with regard to indications for use including recommended filters to be used with Fitzpatrick skin type. Both models are	The indications of the proposed device covered by the

	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.	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. - Treatment of: • 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 telangiectasia, erythema of rosacea, leg veins, spider anglomas and venous malformations. The integrated thermal cooling is indicated for use in cooling the epidermis at	predicate. The cooling system is an integral part of the device.

		the treatment site prior to, during, and after light treatment in general aesthetic dermatologic and plastic surgery procedures. - Reduce pain during light treatment (via partial anesthesia from cooling) - Reduce discomfort during and/or associated with light treatment - Minimize thermal injury, including thermal necrosis, to non-target skin and skin structures during and/or associated with light treatment, thus reducing possible complications such as scabbing, scarring, hyper - and/or hypo pigmentation - Allow the use of higher light or laser fluencies for light treatments (such as for hair removal and the treatment of vascular or pigmented lesions) - Reduce potential side effects of light treatments (such as for hair removal and the treatment of lesions)	
Light source	Intense pulsed light (Xenon Flash Lamp)	Intense pulsed light (Xenon Flash Lamp)	Identical
Wavelength	420 – 1200 nm	420 – 1200 nm	Identical

range			
Hanpiece ports	HS-650K&HS-660K: 2 HS620K, HS-300CK & HS-310K: 1	HS 650: 2 HS 300C: 1	Identical
Structure	HS-650K&HS-660K: Vertical HS620K, HS-300CK & HS-310K: Table top	HS 650: Vertical HS 300C: Table top	Identical
Energy output	4.1-50.8 J/cm^2	10-50 J/cm^2	Equivalent
Pulse width	5-20 ms	2-20 ms	Equivalent
Pulse duration	5-50 ms	5-50 ms	Identical
Spot size	12*35mm, 15*50mm	12*35mm, 15*50mm	Identical
Filters	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;	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;	Identical
Fluences	420 -1200nm: 4.1-50.8J/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: 3.3-37.4J/cm^2; 690-1200nm: 3.1-33.4J/cm^2;	420 -1200nm: 10-50J/cm^2; 510 -1200nm: 9.2-46.35 J/cm^2; 560 -1200nm: 9-42.6 J/cm^2; 610-1200nm: 8.5-38.1 J/cm^2; 640-1200nm: 8-36.8J/cm^2; 690-1200nm: 7.6-32.9J/cm^2;	The fluences for each filter are at similar energy level, considered equivalent.
Output mode	Pulse mode	Pulse mode	Identical

Deliver materials	Direct sapphire Coupling	Direct sapphire Coupling	Identical
Cooling method	HS-650K&HS-660K: Water cooling, forced-air cooling, copper and TEC; HS620K, HS-300CK&HS-310K: Water cooling and forced-air cooling,	TEC and circulating water & air	Equivalent

VII Non-Clinical Testing

A series of tests have been performed to verity that the proposed device met all design specification. The test result demonstrated that the proposed device complies with the following standards:

Electrical safety and electromagnetic compatibility

- 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 60601-1-2:2014 Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-57: 2011 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

Biocompatibility Evaluation:

The contact material of the proposed device is identical to that of the iPulseLight IPL System cleared in K093627.

Per FDA's Biocompatibility Guidance issued on June 16, 2016 and with regard to Table A.1 Evaluation Tests for consideration in ISO, "Use of international Standard ISO 10993-1, Biological evaluation of medical - Part 1: Evaluation and testing within a risk management process," the following tests performed on the material which contacts with human for Biocompatibility:

- Cytotoxicity;
- Skin irritation;
- Skin Sensitization.;

VIII Clinical Testing

It is not applicable.

IX Conclusion

Base on the performance testing and validation studies that the subject device is substantially equivalent to the predicate device.