JAN 2 2 2013

Attachment II 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 21 CFR 807.92.

The assigned 510(k) Number: K122995

1. Date of Submission: September 17, 2012

2. Sponsor

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3. Submission Correspondent

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4. Proposed Device Identification

Proposed Device Name: Intense Pulsed Light (IPL) Systems
Proposed Device Model: MED-210, MED-230

Classification: Class II
Product Code: ONF
Regulation Number: 21 CFR 878.4810
Review Panel: General and Plastic Surgery

Intended Use Statement:

The 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 reduction, treatment of pigmented lesions, moderate inflammatory acne vulgaris, ephelides (freckles), and vascular lesions.

		Skin Types				
Conditions	Filter setting and wavelength rang	I	II	III	IV	V
Hair		640-1200	640-1200	640-1200	690-1200	750-1200
Pigmented lesions		480-1200	530-1200	530-1200	560-1200	560-1200
Acne vulgaris		430-1200	430-1200	430-1200	480-1200	530-1200
Ephelides		480-1200	480-1200	530-1200	530-1200	530-1200
Vascular lesions		530-1200	530-1200	560-1200	560-1200	590-1200

5. Predicate Device Identification

510(k) Number: K093627
Product Name: IPULSELIGHT IPL SYSTEM
Manufacturer: Shanghai APOLO Medical Technology Co., Ltd

6. Device Description

The Intense Pulsed Light (IPL) Systems are intense pulsed light system which delivers intense pulsed light at a wavelength 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.

Based on this, the 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 reduction, treatment of pigmented lesions, moderate inflammatory acne vulgaris, ephelides (freckles), and vascular lesions.

7. Non-Clinical Test Conclusion

Bench 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:

- IEC 60601-1: 1988 +A1:1991+A2:1995, Medical Electrical Equipment – Part 1: General requirements for safety.
- IEC 60601-1-2: 2007, Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic compatibility – Requirements and tests.
- 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.

8. Substantially Equivalent Comparison

Table II-1 SE Comparison

ITEM	Proposed Device Intense Pulsed Light (IPL) Systems	Predicate Device IPULSELIGHT IPL SYSTEM (K093627)
Product Code	ONF	ONF
Regulation No.	21 CFR 878.4810	21 CFR 878.4810
Class	II	II
Intended Use	TheIntense 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 reduction, treatment of pigmented lesions, moderate inflammatory acne vulgaris, ephelides (freckles), and vascular lesions.	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 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 telangiectasias, erythema of rosacea, leg veins, spider anglomas and venous malformations. The integrated thermal cooling is indicated for use in cooling the epidermis at 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 vascular or pigmented lesions)
Light source	Intense pulsed light	Intense pulsed light
Wavelength	430-1200nm, 530-1200nm, 640-1200nm, Optional: 480-1200nm, 560-1200nm, 590-1200nm, 690-1200nm, 750 -1200nm	420nm-1200, 510-1200nm, 560-1200nm, 610-1200nm, 640-1200nm (Standard); 480nm-1200, 585-1200nm, 690-1200nm, 755-1200nm (Options)
Deliver system	Sapphire	Sapphire
Energy density	10-60J/cm^2	10-60J/cm^2
Pulse sequence	1~15 pulses	1~15 pulses
Pulse delay	5 - 50ms	5 - 50ms
Pulse width	1-20ms	2-20ms
Spot size	MED-210: 15mmX50mm (optional: 12mmX33mm, 15mmX35mm) MED-230: A：12mm X33mm; B：15mmX50mm (optional: 15mmX35mm)	12x35mm, 15x50mm (Standard); 12x12mm, 12x25mm, 12x50mm, 15x35mm, 15x45mm (Options)
Power Supply	220V±20V 50Hz or 110V±20V 60Hz	100/110V, 50~60HZ or 230~260V, 50~60HZ
Max. power consumption	MED-210: 1400 W MED-230: 2000 W	1200 W
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2

Table II-2 Setting Comparison of Specified Indication for Use

ITEM	Proposed Device Intense Pulsed Light (IPL) Systems (MED-210, MED-230)	Predicate Device IPULSELIGHT IPL SYSTEM (K093627) (HS 300C, HS 650)
permanent hair reduction		
Wavelength Range (nm)	640-1200/690-1200/ 750-1200	610-1200/640-1200/690-1200
Energy Range (J/cm2)	10-44	10-46
Pulse Duration (ms)	3-14	4-15
Pulse Delay (ms)	16-32	15-30
Spot Size (mm)	12mm X33mm; 15mmX50mm 15mmX35mm	12x25mm,12x35mm, 12x50mm, 15x35mm, 15x45mm
pigmented lesions		
Wavelength Range (nm)	480-1200/530-1200/560-1200	510-1200/560-1200
Energy Range (J/cm2)	12-44	14-46
Pulse Duration (ms)	3-9	2-9
Pulse Delay (ms)	16-32	15-30
Spot Size (mm)	12mm X33mm; 15mmX50mm 15mmX35mm	12x25mm,12x35mm, 12x50mm, 15x35mm, 15x45mm
moderate inflammatory acne vulgaris		
Wavelength Range (nm)	430-1200/480-1200/530-1200	420-1200/510-1200/560-1200
Energy Range (J/cm2)	10-40	10-42
Pulse Duration (ms)	3-8	3-9

Pulse Delay (ms)	16-32	15-30
Spot Size (mm)	12mm X33mm; 15mmX50mm 15mmX35mm	12x25mm,12x35mm, 12x50mm, 15x35mm, 15x45mm
ephelides (freckles)		
Wavelength Range (nm)	480-1200/530-1200	510-1200
Energy Range (J/cm2)	10-42	12-44
Pulse Duration (ms)	3-8	3-9
Pulse Delay (ms)	16-32	15-30
Spot Size (mm)	12mm X33mm; 15mmX50mm 15mmX35mm	12x25mm,12x35mm, 12x50mm, 15x35mm, 15x45mm
vascular lesions		
Wavelength Range (nm)	530-1200/560-1200/ 590-1200	510-1200/560-1200
Energy Range (J/cm2)	10-42	10-44
Pulse Duration (ms)	3-8	3-9
Pulse Delay (ms)	16-32	15-30
Spot Size (mm)	12mm X33mm; 15mmX50mm 15mmX35mm	12x25mm,12x35mm, 12x50mm, 15x35mm, 15x45mm

Difference in intended use, wavelength, spot size, power supply, Max. power consumption and setting of specified indication for use between the proposed and predicate device are discussed in the 510(k) submission documents, it is concluded that these differences will not affect the effectiveness and safety of the proposed device.

The proposed device, Intense Pulsed Light (IPL) Systems, are determined to be Substantially Equivalent (SE) to the predicate device, IPULSELIGHT IPL SYSTEM (K093627), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Beijing Kes Biology Technology Company, Limited
% Mid-Link Consulting Company, Limited
Ms. Diana Hong
Correspondent, General Manager
P.O. Box 237-023
Shanghai, China 200237

January 22, 2013

Re: K122995
Trade/Device Name: Intense Pulsed Light (IPL) Systems
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: ONF
Dated: December 26, 2012
Received: December 31, 2012

Dear Ms. Hong:

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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section II Indications for Use

510(k) Number:
Device Name: Intense Pulsed Light (IPL) Systems

Indications for Use:

The 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, skin rejuvenation, reduction of pigmented lesions, acne therapy, freckle, vascular lesions and facial blemish removal.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.01.18 08:52:24 -05'00'

(Division Sign-Off)

Division of Surgical Devices

510(k) Number K122995