DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 4, 2016

Beijing Adss Development Co., Ltd
% Ray Wang
General Manager
Beijing Believe Technology Services Co., Ltd.
5-1206, Build 332, Dafangju, No.25 Banbidian Rd.
Liyuan Town, Tongzhou District, Beijing, 101121 CN

Re: K161286
Trade/Device Name: Ipl Therapy Machine
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: May 3, 2016
Received: May 9, 2016

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. 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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Christopher J. Ronk -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161286

Device Name
IPL Therapy Machine

Indications for Use *(Describe)*

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

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Tab #7 510(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: K161286

1. Date of Preparation: 07/31/2016

2. Sponsor Identification

Beijing ADSS Development Co., Ltd

F6, Xiandao Bldg., Jinyuan Rd. 36, Daxing Economic Development zone, Beijing, China, 102628

Establishment Registration Number: Not yet registered or the Number

Contact Person: Gao Yurong
Position: sales manager
Tel: 86-10-83625120
Fax:86-10-83625121
Email: gyr@adss.com.cn

3. Designated Submission Correspondent

Mr. Ray Wang

Beijing Believe Technology Service Co., Ltd.
5-1206, Build 332, DaFangJu, No.25 BanBiDian Rd.,
LiYuan Town, TongZhou District, Beijing, 101121, China

Tel: +86-10-59120817
Fax: +86-10-52214696
Email: ray.wang@believe-med.com

4. Identification of Proposed Device

Trade Name: IPL Therapy Machine
Common Name: Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Model(s): VE2000

Regulatory Information:
Classification Name:
Laser surgical instrument for use in general and plastic surgery and in dermatology；
Classification: II;
Product Code: ONF;
Regulation Number: 21 CFR 878.4810；
Review Panel: General & Plastic Surgery;

Intended Use Statement:

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.

		Skin Types		
Conditions	Filter setting and wave length rang	I	II	III
hair removal		640-1200	640-1200	640-1200
pigmented lesions		480-1200	480-1200	480-1200
vascular lesions		590-1200	590-1200	590-1200

Device Description:
The VE2000 device are intense pulsed light system which delivers intense pulsed light at a wavelength ranging from 480nm-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 VE2000 device (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 and vascular lesions.

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:

a)IEC 60601-1-2:2007, 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

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 9-1 General Comparison

ITEM	Proposed Device VE2000	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 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	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 9-2 Performance Comparison

ITEM	Proposed Device VE2000	Predicate Device Intense Pulsed Light (IPL) Systems(K122995)	Remark
Light source	Intense pulsed light	Intense pulsed light	SE
Wavelength	480nm—1200nm 590nm—1200nm 640nm—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	1-50J/cm²	10-60J/cm^2	Analysis 1
Pulse Delay	1-50ms	5 - 50ms	Analysis 1
Pulse Width	1-25ms	1-20ms	Analysis 1
Max. Power	2200W	2000 W	SE
Spot size	12x30mm	MED-210: 15mmX50mm (optional: 12mmX33mm, 15mmX35mm) MED-230: A：12mm X33mm; B：15mmX50mm (optional: 15mmX35mm)	Analysis 1

Table 9-3 Setting Comparison of Specified Indication for Use

ITEM	Proposed Device VE2000	Predicate Device Intense Pulsed Light (IPL) Systems(K122995)	Remark
permanent hair reduction			
Wavelength Range (nm)	640-1200	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)	12x30mm	12mm X33mm; 15mmX50mm 15mmX35mm	
pigmented lesions			
Wavelength Range (nm)	480-1200	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)	12x30mm	12mm X33mm; 15mmX50mm 15mmX35mm	
vascular lesions			
Wavelength Range (nm)	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)	12x30mm	12mm X33mm; 15mmX50mm 15mmX35mm	

Analysis 1:

The Energy density, Pulse width and Pulse delay of proposed device is very similar to that of predicate device, the difference is very slight, and only in the range, but because the proposed device has narrow IFU scope and same IFU setting with the predicate device, the current parameter range is available for the indication for use of proposed device. Therefore, the slight difference is considered to have no effect on effectiveness and safe.

Table 9-4 Safety Comparison

ITEM	Proposed Device VE2000	Predicate Device Intense Pulsed Light (IPL) Systems(K122995)	Remark
Power supply	110V 50Hz	220V±20V 50Hz or 110V±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	Handpiece	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	The test article showed no signification evidence of	SE

	causing skin sensitization in the guinea pig .(ISO 10993-10)	causing skin sensitization in the guinea pig .(ISO 10993-10)	

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.