DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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February 22, 2017

Beijing Adss Development Co., Ltd
% 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

Re: K161926
Trade/Device Name: Nd Yag Q-switch Laser 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: GEX
Dated: January 18, 2017
Received: January 23, 2017

Dear Mr. 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,

Jennifer R. Stevenson -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)*
K161926

Device Name
ND YAG Q-switch Laser Therapy Machine

Indications for Use *(Describe)*

The ND YAG Q-switch Laser Therapy Machine is indicated for the treatment of: benign cutaneous lesions, such as Warts, Scars, Striae and Psoriasis; benign pigmented lesions, such as Lentigines, nevus, and birthmark; and the removal of black or blue tattoos.

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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Tab #3 510(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: K161926

1. Date of Preparation

   02/16/2017

2. Sponsor

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. 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: +86-18910677558
Fax: +86-10-52214696
Email: ray.wang@believe-med.com

4. Identification of Proposed Device

Trade Name: ND YAG Q-switch Laser Therapy Machine
Common Name: Powered Laser Surgical Instrument
Model(s): FG 2010, FG 2010-B, FG 2010-C

Regulatory Information:
Classification Name: Powered Laser Surgical Instrument
Classification: II;
Product Code: GEX;
Regulation Number: 21 CFR 878.4810;
Review Panel: General& Plastic Surgery;

Intended Use:

The ND YAG Q-switch Laser Therapy Machine is indicated for the treatment of: benign cutaneous lesions, such as Warts, Scars, Striae and Psoriasis; benign pigmented lesions, such as Lentigines, nevus, and birthmark; and the removal of black or blue tattoos.

5. Device Description

The ND YAG Q-switch Laser Therapy Machine is laser system which delivers laser at a wavelength 1064nm or 532nm.

There are 3 models included, FG 2010, FG 2010-B, FG 2010-C, the three models have same intended use, mechanism of action, principle and specification, only differences are the configurations. The detailed difference shown as following:

Table 1 The Difference of Models

Model	FG2010	FG2010-B	FG2010-C
Size	860×310×830mm	800×320×920mm	830×320×830mm
Weight	60kg	65kg	60kg

Table 2 Main Components introduction

Component name	Function
Main unit	Main Interface
Articulated Arm	Articulated arm for holding of Treatment Probe
Treatment Probe	Laser Deliver
Foot Pedal	control pulse light output

6. Identification of Predicate Device

Predicate Device：
510(k) Number
K072564

Predicate Device Name
Harmony XL Multiple Application Platform

Manufacturer
Alma Laser, Ltd

7. Non-Clinical Test

Non clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- IEC 60601-2-22:2007, Medical Electrical Equipment - Part 2-22: Particular Requirements For Basic Safety And Essential Performance Of Surgical, Cosmetic, Therapeutic And Diagnostic Laser Equipment;
- IEC 60825-1: 2007, Safety of laser products - Part 1: Equipment classification and requirements.
- 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 Device, Part 5-Tests for Vitro cytotoxicity
- ISO 10993-10:2002/Amd. 1: 2006, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity AMENDMENT 1
- Performance Testing for Spot Size Accuracy.
- Thermal Energy Distribution Test: determine the difference for thermal energy distribution of proposed device with predicate device.

8. Clinical Test

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 3 General Comparison

ITEM	**Proposed Device**	**Predicate Device** K072536	Remark
Product Code	GEX	GEX	SE
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SE
Class	2	2	SE
Intended Use	The ND YAG Q-switch Laser Therapy Machine is indicated for the treatment of: benign cutaneous lesions, such as Warts, Scars, Striae and Psoriasis; benign pigmented lesions, such as Lentigines, nevus, and birthmark; and the removal of black or blue tattoos.	The 1064 nm Long Pulsed and Q-switched Nd:YAG Laser Module Handpieces The 1064 nm Nd:YAG Laser Module handpiece (Long Pulsed and Q-switched with and without contact-cooling) are indicated for treatment and clearance of • Benign vascular lesions such as, but not limited to treatment of: ➢ Port wine stains ➢ Hemangiomas ➢ Warts ➢ Superficial and deep telangiectasias (venulectasias) ➢ Reticular veins (0.1-4.0 mm dia.) of the leg ➢ Rosacea ➢ Venus lake ➢ Leg veins ➢ Spider veins ➢ Angiomas • Benign cutaneous lesions, such as, but not limited to : ➢ Warts ➢ Scars ➢ Striae ➢ Psoriasis • Benign pigmented lesions such as, but not limited to: ➢ Lentigos (age spots) ➢ Solar lentigos (sun spots) ➢ Café-au- lait birthmarks ➢ Seborrheic keratoses ➢ Nevi and nevus of Ota ➢ Chloasma ➢ Verrucae	SE

		➢ Skin tage ➢ Keratoses ➢ The removal of black, blue or green tattoos (significant reduction in the intensity of black and /or blue tattoos) ➢ Plaques • Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. • The non-ablative treatment of facial wrinkles, such as, but not limited to: ➢ Periocular wrinkles ➢ Perioral wrinkles • Laser skin resurfacing procedures for the treatment of: ➢ Acne scars ➢ Wrinkles • Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin	

Table 4 Performance Comparison

ITEM	**Proposed Device**	**Predicate Device 2** K072536	Remark
Laser Medium	Nd:YAG	Nd:YAG	SE
wavelength	1064 nm 532 nm	1064 nm 532 nm	SE
Output energy	100-1000mJ for 1064nm 50-500mJ for 532nm	400-1200mJ	SE
Max. Energy Density	31.8J/cm^2 15.9 J/cm^2	16.9 J/cm^2	SE
Spot Size	2-10mm	3, 5 mm	Analysis

Pulse Width	5ns-8ns	20 ns	Analysis
Repetition Rate	1-10 Hz	1, 2, 4 Hz	Analysis
Disinfection	Disinfect the handpiece before and after every treatment by 75% medicinal alcohol	---	Analysis
Laser Class	Class 4	Class 4	SE
Cooling method for treated skin area	N.A.	N.A.	SE
Aiming Beam	Red Laser, <6mW	N.A	Analysis

Table 5 Safety Comparison

Item	**Proposed Device**	**Predicate Device** K072536	**Remark**
Patient Contact Materials and Biocompatibility			
Patient Contact Materials	Treatment Probe (Stainless Steel)	Treatment Probe (Stainless Steel)	SE
Cytotoxicity	No Cytotoxicity	Comply with ISO 10993-1	SE
Sensitization	No evidence of sensitization		
Irritation	No evidence of irritation		
EMC, Electrical and Laser Safety			
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Laser Safety	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	SE

Analysis for difference

The proposed device is substantially equivalent to the predicate device. Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.

10. Substantially Equivalent (SE) Conclusion

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