DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 2, 2017

Beijing Sincoheren Science And Technology Development Co.
% Mike Gu
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Services Co.,ltd.
8-9th Floor, R&d Building, No.26 Qinglan St, Panyu District
Guangzhou, 510006 CN

Re: K163123
Trade/Device Name: Q-switched Nd:YAG Laser Therapy 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: GEX
Dated: October 31, 2016
Received: November 8, 2016

Dear Mike Gu:

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)*
K163123

Device Name

Q-Switched Nd: YAG Laser Therapy Systems

Indications for Use *(Describe)*

The Q-Switched Nd: YAG Laser Therapy System (1064nm or 532nm) is indicated for use in tattoo removal, treatment of benign vascular lesions, treatment of benign pigmented lesions, incision, excision, ablation, vaporization of soft tissue for general dermatology as follows:

1064nm:
-Tattoo Removal
Dark ink: blue and black.
-Treatment of Benign Pigmented Lesions
Nevus of ota.

532nm:
-Tattoo Removal
Light ink: red.
Light ink: sky blue and green.
- Treatment of Benign Vascular Lesions
Port wine birthmarks; Telangiectasias; Spider angioma; Cherry angioma; Spider nevi.
-Treatment of Benign Pigmented Lesions
Cafe-au-lait birthmarks; Solar lentiginos; Senile lentiginos; Becker's nevi; Freckles; Nevus spilus.

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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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER

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Secondary Contact Person:	Huan Kong Regulatory Affairs Engineer Beijing Sincoheren Science and Technology Development Co., Ltd. Tel: (+86) 10-62277431-8009 Fax: (+86) 10-82290050
Date prepared:	Oct 31, 2016

II. DEVICE

Name of Device:	Q-Switched Nd: YAG Laser Therapy Systems
Common/Usual Name:	YAG Laser Therapy Systems
Classification Names:	Powered Laser Surgical Instrument (21 CFR 878.4810)
Regulation Class:	II
Product Code:	GEX

III. PREDICATE DEVICE

Nd: YAG Laser System, K133158

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Q-Switched Nd:YAG Laser Systems is based on the Q-Switched Nd: YAG (1064 nm) and frequency doubled KTP Nd: YAG (532nm) Laser Technology. There is one optical cavity containing the Nd: YAG Crystal. It is composed of laser module, articulated arm, laser power supply, cooling system and display and control system.

The Q-Switched Nd: YAG Laser Therapy Systems works based on laser selective photothermy and blasting mechanism of Q-switched laser. Energy form particular wavelength with accurate dose will act on certain targeted color radicals: ink, carbon particles from derma and epidermis, exogenous pigment particles and endogenous melanophore from derma and epidermis. When suddenly being heated, pigment particles immediately blast into smaller pieces, which will be swallowed by macrophage phagocytosis and enters into lymph circulation system and finally be discharged out of body.

The physician is able to select the desired wavelength and the related output energy, spot size and fluency via control panel.

V. IDICATIONS FOR USE

The Q-Switched Nd: YAG Laser Therapy System (1064nm or 532nm) is indicated for use in tattoo removal, treatment of benign vascular lesions, treatment of benign pigmented lesions, incision, excision, ablation, vaporization of soft tissue for general dermatology as follows:

1064nm:
-Tattoo Removal
Dark ink: blue and black.
-Treatment of Benign Pigmented Lesions
Nevus of ota.
532nm:
-Tattoo Removal
Light ink: red.
Light ink: sky blue and green.
- Treatment of Benign Vascular Lesions
Port wine birthmarks; Telangiectasias; Spider angioma; Cherry angioma; Spider nevi.
-Treatment of Benign Pigmented Lesions
Cafe-au-lait birthmarks; Solar lentiginos; Senile lentiginos; Becker's nevi; Freckles; Nevus spilus.

VI. TECHNOLOGY

The Q-Switched Nd: YAG Laser Therapy Systems works based on the principles of laser selective photothermy and blasting mechanism of Q-switched laser. Energy from particular wavelength with accurate dose act on certain targeted color radicals: ink, carbon particles from derma and epidermis, exogenous pigment particles and endogenous melanocytes from derma and epidermis. When suddenly being heated, pigment particles immediately blast into smaller pieces, which will be swallowed by macrophage phagocytosis and enter into lymph circulation system and finally be discharged out of the body.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Specification	**Predicate device**	**Proposed device**	**Discussion of Differences**
K number	K133158	--	
Product Code	GEX		Identical
Manufacturer	Beijing Toplaser Technology Co., Ltd	Beijing Sincoheren Science and Technology Development Co., Ltd.	
Device name	Nd: YAG Laser System	Q-Switched Nd: YAG Laser Therapy Systems	Similar
Indications for use	**1064nm:** -Tattoo Removal ✧ Dark ink: blue and black -Treatment of Benign Pigmented Lesions ✧ Nevus of ota **532nm:** -Tattoo Removal ✧ Light ink: red ✧ Light ink: sky blue and green - Treatment of Benign Vascular Lesions ✧ Port wine birthmarks; Telangiectasias; Spider angioma; Cherry angioma; Spider nevi -Treatment of Benign Pigmented Lesions ✧ Cafe-au-lait birthmarks; Solar lentiginos; Senile lentiginos; Becker's nevi; Freckles; Nevus spilus. ✧		Identical
Technology	Q-Switched ND:YAG and KTP Nd: YAG Laser	Q -Switched ND:YAG and KTP Nd: YAG Laser	Identical
Energy Source	Xenon Lamp	Xenon Lamp	Identical
Wavelength (nm)	1064nm and 532nm		Identical
Aiming beam wavelength	635nm		Identical

Specification	Predicate device	Proposed device	Discussion of Differences
Laser output mode	Q-switched pulse	Q-switched pulse	Identical
Aiming laser output power	<5mw	0.1-5mw	Identical
Maximum Pulse Energy	@1064nm wavelength: 1--~1000mJ @532nm wavelength: 50-300mJ	@1064nm wavelength: 500mJ @532nm wavelength: 250mJ	Less than Predicate device , more safe
Pulse Duration	6~8ns	5ns±1ns or 5ns	Less Pulse Duration, more peak power, more effective
Repetition Rate	1~10Hz	1-5Hz	Less than Predicate device, more safe
Nominal ocular hazard distance	NOHD 2.8km	NOHD 3.3km	Similar
Spot Size	Adjustable Spot Size 3-9 mm(Diameter)	Adjustable Spot Size 2-10 mm(Diameter)	Wider adjustable range of spot size than predicate device, more useful
Material	Steel, ABS	Steel, ABS	Identical
Beam delivery	Articulating Arm Light Guide	Articulating Arm Light Guide	Identical
Cooling	Internal distilled water circulating cooling	Internal distilled water circulating cooling	Identical
Anatomical Sites	Skin and subcutaneous tissue	Skin and subcutaneous tissue	Identical

VIII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Q-Switched Nd: YAG Laser Therapy Systems was conducted in accordance with the guidance “Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process” as recognized by FDA. The biocompatible testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The handpiece is considered skin and subcutaneous tissue contacting for a duration of less than 24 hours.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Q-Switched Nd: YAG Laser Therapy Systems. The device complies with the IEC 60601-1, standard for safety and the IEC 60601-1-2 standard for EMC.

Performance testing

Performance testing was conducted on the device according to IEC 60825-1.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Animal Study

The subject of this premarket submission, Q-Switched Nd: YAG Laser Therapy Systems, does not require animal studies to support substantial equivalence.

Clinical Study

The subject of this premarket submission, Q-Switched Nd: YAG Laser Therapy Systems, did not require clinical studies to support substantial equivalence.

IX. CONCLUSION

The non-clinical data support the safety of the device and the performance testing report demonstrate that the Q-Switched Nd: YAG Laser Therapy Systems should perform as intended in the specified use conditions. Beijing Sincoheren considers the Q-Switched Nd: YAG Laser Therapy Systems to be substantially equivalent to the predicate device and does not raise any new issues of safety or effectiveness.