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

June 17, 2019

Re: K190936
Trade/Device Name: Q-Switched Nd: YAG Laser System
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: April 4, 2019
Received: April 10, 2019

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,

Neil R.P. Ogden, MS
Acting Assistant Director, THT4A3: Light Based Devices Team
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)*
K190936

Device Name
Q-Switched Nd: YAG Laser Systems

Indications for Use *(Describe)*
The Q-Switched Nd: YAG Laser System is intended 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:

532nm wavelength (nominal delivered energy of 585nm and 650nm with optional dye handpiece):
- Removal of light ink (red, sky blue, green, purple, and orange) tattoo
- Treatment of benign vascular lesions including, but not limited to: telangiectasias,
- Treatment of benign epidermal pigmented lesions including, but not limited to: cafe-au-lait, solar lentiginos, senile lentiginos, Becher's, nevi Freckles, Nevus spilus, Seborrheic Keratoses
- Treatment of Post Inflammatory Hyper-Pigmentation

1064nm wavelength:
- Removal dark ink (black, blue and brown) tattoo
- Removal of benign dermal pigmented lesions including, but not limited to: Nevus of OTA, Common Nevi, and Melasma,
- Removal or lightening of unwanted hair with or without adjuvant preparation
- Skin resurfacing procedures for the treatment of acne scars and wrinkles.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"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."*

# 510(k) Summary

## I Submitter

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

Establishment Registration Number: 3007120647

Contact person: Felix Li
Position: Regulatory Affairs
Phone: +86-138 4919 0618
Fax: +86-21-34622840
E-mail: liqiang@apolo.com.cn

## II Proposed Device

| | |
|---|---|
| Trade Name of Device: | Q-Switched Nd: YAG Laser System |
| Common name: | Powered Laser Surgical Instrument |
| Regulation Number: | 21 CFR 878.4810 |
| Regulatory Class: | Class II |
| Product code: | GEX |
| Review Panel | General & Plastic Surgery |

## III Predicate Devices

| | |
|---|---|
| 510(k) Number: | K113588 |
| Trade name: | SPECTRA Q-Switched Nd:YAG Laser System with Dye Handpieces |
| Common name: | Powered Laser Surgical Instrument |
| Classification: | Class II |
| Product Code: | GEX |
| Manufacturer | Lutronic Corporation |

## IV Device description

The Q-Switched Nd: YAG Laser System is based on the Q-Switch Nd: YAG and frequency-double Nd:YAG laser technology. The system is composed of laser generator,

articulated arm, laser power supply, cooling system, display and control system,foot switch and others accessories.

The Q-Switched Nd: YAG Laser System produces a pulsed beam of coherent near infrared (1064nm) and visible (532nm) light. This beam is directed to the treatment zone by means of an articulated arm coupled to a handpiece. In addition, two dye handpieces are available that concert the 532nm wavelength to 585nm and 650nm.

The Q-Switched Nd: YAG Laser System includes two models: HS-290K and HS-290EK.

**V Indication for use**

The Q-Switched Nd: YAG Laser System is intended 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:

**532nm wavelength (nominal delivered energy of 585nm and 650nm with optional dye handpiece):**

- Removal of light ink (red, sky blue, green, purple, and orange) tattoo,
- Treatment of benign vascular lesions including, but not limited to: telangiectasias,
- Treatment of benign epidermal pigmented lesions including, but not limited to: cafe-au-lait, solar lentiginos, senile lentiginos, Becher's, nevi Freckles, Nevus spilus, Seborrheic Keratoses,
- Treatment of Post Inflammatory Hyper-Pigmentation.

**1064nm wavelength:**

- Removal dark ink (black, blue and brown) tattoo,
- Removal of benign dermal pigmented lesions including, but not limited to: Nevus of OTA, Common Nevi, and Melasma,
- Removal or lightening of unwanted hair with or without adjuvant preparation,
- Skin resurfacing procedures for the treatment of acne scars and wrinkles.

**VI Comparison of technological characteristics with the predicate devices**

A table comparing the key features of the proposed and predicate devices is provided below.

| **Item** | **Subject device** | **Predicate device (K113588)** |
|---|---|---|
| Product name | Q-Switched Nd: YAG Laser System | SPECTRA Q-Switched Nd:YAG Laser System with Dye Handpiece |
| Product Code | **GEX** | **GEX** |

| Regulation No. | 21 CFR 878.4810 | 21 CFR 878.4810 |
|---|---|---|
| Class | Class II | Class II |
| Indication for use | The Q-Switched Nd: YAG Laser System is intended 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:<br><br>**532nm wavelength (nominal delivered energy of 585nm and 650nm with optional dye handpiece):**<br>• Removal of light ink (red, sky blue, green, purple, and orange) tattoo<br>• Treatment of benign vascular lesions including, but not limited to: telangiectasias,<br>• Treatment of benign epidermal pigmented lesions including, but not limited to: cafe-au-lait, solar lentiginos, senile lentiginos, Becher's, nevi Freckles, Nevus spilus, Seborrheic Keratoses<br>• Treatment of Post Inflammatory Hyper-Pigmentation<br><br>**1064nm wavelength:**<br>• Removal dark ink (black, blue and brown) tattoo<br>• Removal of benign dermal pigmented lesions including, but not limited to: Nevus of OTA, Common Nevi, and Melasma, | The SPECTRA Laser System is indicated for the Incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedure for coagulation and hemostasis.<br><br>532nm Wavelength (normal delivered energy of 585nm and 650nm with optional dye handpieces):<br>• Tattoo removal: light ink (red, tan, purple, orange, sky blue, green)<br>• Removal of Epidermal Pigment Lesions<br>• Removal of Minor Vascular Lesions including but not limited to telangiectasias<br>• Treatment of Lentigines<br>• Treatment of Café-Au-lait<br>• Treatment of Post Inflammatory Hyper-Pigmentation<br>• Treatment of Becker’s Nevi, Freckles and Nevi Spilus<br>1064nm Wavelength<br>• Tattoo removal: dark ink (black, blue and brown)<br>• Removal of Epidermal Pigment Lesions<br>• Removal of Nevus of Ota |

| | | |
|---|---|---|
| | • Removal or lightening of unwanted hair with or without adjuvant preparation<br>• Skin resurfacing procedures for the treatment of acne scars and wrinkles | • Removal or lightening of unwanted hair with or without adjuvant preparation<br>• Treatment of Common Nevi<br>• Skin resurfacing procedure for the treatment of acne scars and wrinkle<br>• Treatment of melasma. |
| Anatomical site | Skin and subcutaneous tissue | Skin and subcutaneous tissue |
| Technology | Q-Switched Nd: YAG amd KTP Nd:YAG Laser | Q-Switched Nd: YAG amd KTP Nd:YAG Laser |
| Pump lamp source | Xenon lamp | Xenon lamp |
| Wavelength (nm) | 1064nm/532nm | 1064nm/532nm |
| Aiming beam wavelength | 650nm | 655nm |
| Laser output mode | Q-Switched pulse | Q-Switched pulse |
| Maximum pulse energy | 1064nm wavelength: 1200mJ；<br>532nm wavelength:500mJ<br>SPT mode: 1400mJ | 1064nm wavelength: 1200mJ；<br>532nm wavelength:400mJ<br>SPT mode: 1500mJ |
| Pulse duration | 4~6ns（Q-Switched mode）/300μs（SPT mode） | 5~10nsQ-Switched mode）/300μs （Spectra mode） |
| Repetition rate | Max,10Hz | Max,10Hz |
| Nominal ocular hazard distance | 2580m | unknown |
| Spot size | Adjustable spot size 1~10mm | 3, 4, 5, 6, 7, 8mm/1, 2, 3, 4, 5, 6, 7mm (option) |
| Beam delivery | Articulated arm light guide | Articulated arm light guide |
| Cooling system | Water cooling, forced-air cooling, Copper Radiator | Closed internal circulating water cooling, outer circulation |

| | | |
|---|---|---|
| | | strong wind cooling |
| System dimension | HS-290K: 11.8”(W)×32.7”(L)×34.6”(H) HS-290EK: 11.8”(W)×29.5”(L)×34.6”(H) | 11.6”(W)×25.8”(L)×66.93”(H) |
| System weight | HS-290K: 176.4lbs HS-290EK: 167.6 lbs | 194lbs |
| Electrical requirements | AC 110V, 50/60Hz | AC 220-230V, 50/60Hz |
| Maximum power | 200MW | 240MW |

**VII Non-Clinical Testing**

A battery of tests were 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 60601-2-22:2013 Medical electrical equipment - Part 2-22: Particular requirements for the 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

**VIII Clinical Testing**

It is not applicable.

**IX Conclusion**

The proposed device, Q-Switched Nd: YAG Laser System has the same the intended use as the predicate device. It presents similar technological characteristics as the predicate device including the laser type, wavelengths, device design, pulse width, frequency, spot sizes. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.