



November 16, 2020

Shangdong Huamei Technology Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHei, No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
China

Re: K202758

Trade/Device Name: Nd: YAG Laser Therapy Systems HM-YL900

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: September 18, 2020

Received: September 21, 2020

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. 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 and Part 809); 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,

Purva Pandya
Acting Assistant Director
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

Indications for Use

510(k) Number (if known)
K202758

Device Name
Nd: YAG Laser Therapy Systems
Model: HM-YL900

Indications for Use (Describe)

The Nd: YAG Laser Therapy Systems 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:

- * 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, Becker'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.

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510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Section 807.92.

1. Date of Preparation

11/06/2020

2. Applicant Name and Address

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4. Submission Correspondent

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5. Identification of Proposed Device

Trade Name: Nd: YAG Laser Therapy Systems, Model: HM-YL900
Common Name: Powered Laser Surgical Instrument
Model(s): HM-YL900

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Class: II

Product Code: GEX

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Review Panel: General & Plastic Surgery

6. Identification of the Predicate and Reference Devices

Primary Predicate

510(k) Number: K190936

Device Name: Q-Switched Nd: YAG Laser System

Manufacturer: Shanghai Apolo Medical Technology Co., Ltd.

Reference Device #1
510(k) Number: K122922
Product Name: E-beam Nd: YAG Laser System
Manufacturer: ECLIPSE AESTHETICS, LLC

Reference Device #2
510(k) Number: K113588
Product Name: SPECTRA LASER SYSTEM
Manufacturer: LUTRONIC CORPORATION

7. Device Description

The Nd: YAG Laser Therapy Systems 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.

The Nd: YAG Laser Therapy Systems includes five modules described as following:

Control Panel

The module uses the microcontroller as the heart, utilizes the LCD screen to display all prompt information and the system state information to complete the human-machine interaction function, and realizes the device parameters setting and accurate control of the output laser energy by the operator.

Main Control Module

The module uses the microcontroller as the heart, receives the laser energy parameters and work command from the control panel and detects the state of footswitch and interlock switch; Controls the work state of laser RF power supply; Uploads the alarm information of footswitch and interlock switch during system working.

Auxiliary Control Module

The module is mainly composed of bi-color indicator and super-quiet adjustable air pump and other components; its working state is determined by the command from the main control module to meet the device requirements, and independently monitor the DC power module output.

Laser, laser RF power supply and DC power supply module

The module completes the YAG laser emission according to the command from the control panel.

Light arm module

The light arm module is the output part of the device, which consists of a socket for light arm, a light arm, the joint for light arm, a hard film reflector and a focusing lens and a handpiece

8. Indications for Use

The Nd: YAG Laser Therapy Systems 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:

- 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, Becker'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

9. Substantially Equivalent (SE) Comparison

Tab 1 General Comparison

ITEM	Proposed Device	Predicate Device K190936	Reference Device K122922	Reference Device K113588	Remark
Product Code	GEX	GEX	GEX	GEX	SAME
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	SAME
Class	2	2	2	2	SAME
Where used	hospital	hospital	hospital	hospital	SAME
Indication For Use	<p>The Nd: YAG Laser Therapy Systems 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:</p> <p>532nm wavelength:</p> <ul style="list-style-type: none"> ● 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 <p>1064nm wavelength:</p> <ul style="list-style-type: none"> ● 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 	<p>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:</p> <p>532nm wavelength (nominal delivered energy of 585nm and 650nm with optional dye handpiece):</p> <ul style="list-style-type: none"> ● 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 <p>1064nm wavelength:</p> <ul style="list-style-type: none"> ● 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 	<p>The Tri-Beam Nd:YAG Laser System in indicated for: the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.</p> <p>532nm Wavelength (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces):</p> <ul style="list-style-type: none"> -Tattoo removal: light ink (red, tan, purple, orange, sky blue, green) - Removal of Epidermal Pigmented Lesions -Removal of Minor Vascular Lesions including but not limited to telangiectasias -Treatment of Lentiginos; -Treatment of Caf6-Au-Lait -Treatment of Seborrheic Keratoses - Treatment of Post Inflammatory Hyper-Pigmentation -Treatment of Becker's Nevi, Freckles and Nevi Spilus <p>1 064nm Wavelength:</p> <ul style="list-style-type: none"> -Tattoo removal: dark ink (black, blue and brown) -Removal of Nevus of Ota -Removal or lightening of unwanted hair with or without adjuvant preparation. - Treatment of Common Nevi -Skin resurfacing procedures for the treatment of acne scars and wrinkle 	<p>The SPECTRA Laser System is indicated for the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.</p> <p>532nm Wavelength (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces):</p> <ul style="list-style-type: none"> -Tattoo removal: light ink (red, tan, purple, orange, sky blue, green) - Removal of Epidermal Pigmented Lesions -Removal of Minor Vascular Lesions including but not limited to telangiectasias -Treatment of Lentiginos -Treatment of Caf6-Au-Lait -Treatment of Seborrheic Keratoses - Treatment of Post Inflammatory Hyper -Pigmentation -Treatment of Becker's Nevi, Freckles and Nevi Spilus <p>1064nmr Wavelength:</p> <ul style="list-style-type: none"> -Tattoo removal: dark ink (black, blue and brown) -Removal of Nevus of Ota -Removal or lightening of unwanted hair with or without adjuvant preparation. - Treatment of Common Nevi -Skin resurfacing procedures for the treatment of acne scars and wrinkle - Treatment of melasma. 	SAME

	wrinkles	treatment of acne scars and wrinkles		
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Tab 2 Performance Comparison

ITEM	Proposed Device	Predicate Device K190936	Reference Device K122922	Reference Device K113588	Remark
Laser Medium	Nd:YAG	Nd:YAG	Nd:YAG	Nd:YAG	SAME
Wavelength	1064 nm 532 nm	1064 nm 532 nm	1064 nm 532 nm	1064 nm 532 nm	SAME
Aiming Beam Wavelength	650 nm	650 nm	655 nm	655 nm	SAME
Output energy	1000mJ for 1064nm 500mJ for 532nm	1200mJ for 1064nm 500mJ for 532nm	1200mJ for 1064nm 400mJ for 532nm	1200mJ for 1064nm 400mJ for 532nm	Analysis
Fluence	1.27 - 31.8 J/cm ² for 1064nm 0.6 - 15.9 J/cm ² for 532nm	1.52 - 152.9 J/cm ² for 1064nm 0.6 - 63.7 J/cm ² for 532nm	2.38-38.21J/cm ² for 1064nm 0.6-1.42 J/cm ² for 532 nm	3.12-16.98J/cm ² for 1064nm 0.4-12.7 J/cm ² for 532 nm	Analysis
Spot Size	2-10mm	1-10mm	2-8 mm for 1064 nm 6-9mm for 532 nm	3,4,5,6,7,8 mm	Similar
Pulse Width	4ns-6ns	4ns-6ns	5-10ns	5-10ns	SAME
Frequency	10 Hz Max.	10 Hz Max.	10Hz Max.	10Hz Max.	SAME
Laser Class	Class 4	Class 4	Class 4	Class 4	SAME

Difference Analysis

There difference in Output Energy, Spot Size and Fluence between the proposed device and predicate (reference) device(s).

The difference on Output Energy and Spot Size would not impact the safety and effectiveness, because the final safety and effectiveness about clinical indications will depends on the amount of energy output per unit area, which would produce thermal effects to the patient’s skin area irradiated to achieve claimed indication for use.

For the difference on Fluence listed between the predicate and reference device(s) in Table 2 above, we can see that the proposed device has similar minimum fluence with predicate device (K190936), 1.27 J/cm² VS. 1.52 J/cm² (for 1064 nm) and 0.6 J/cm² VS. 0.6 J/cm² (for 532 nm), they are same and only with minor difference for 1064nm.

The major difference is maximum fluence between the proposed device and with predicate device (K190936), 31.8J/cm² VS. 152.9 J/cm² (for 1064 nm) and 15.9 J/cm² VS. 63.7 J/cm² (for 532nm). The maximum fluences of proposed device are way smaller than the predicate device, which means the proposed device would not raise the risk relating to safety, because the smaller fluences means smaller thermal risk.

But smaller raise will raise the concerns about effectiveness, so we conducted the other two reference devices with same indication for use and similar specification with proposed device in comparison, K122922 and K113588.

After comparison in Table 2 above, the maximum fluence for 1064 nm of proposed device is similar with reference device K122922, 31.8J/cm² VS. 38.21J/cm², and bigger than the reference device K113588, 31.8J/cm² VS. 16.98J/cm².

And in the same way, the maximum fluence for 532 nm of proposed device is similar with the reference device K113588, 15.9J/cm² VS. 12.71J/cm², and similar the reference device K122922, 15.9J/cm² VS. 1.42J/cm².

Which means the cleared devices (K122922 and K113588) with similar or smaller maximum influence could achieve the indication for use same with the proposed device. Which is demonstration of that the maximum fluence of proposed could achieve its indication for use without effectiveness concerns.

Tab 3 Safety Comparison

Item	Proposed Device	Predicate Device K190936	Remark
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	SAME
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SAME
Laser Safety	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	SAME

10. Non-Clinical Testing

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:

- IEC 60601-1:2005/A1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- IEC 60601-2-22:2012, 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: 2014, Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 60601-1-2:2014, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests.

In Addition, the following non-clinical tests were performed to make sure that the device performs as intended:

- Software Validation & Verification Test as following:
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 "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

11. Clinical Testing

No clinical study is performed to support substantial equivalence.

12. Conclusion

Based on the comparison and analysis above, the proposed device is determined to be as safe, as effective, and performs as well as the legally marketed predicate and reference devices.