June 12, 2024

AMI Inc.
% Alexander Henderson
Official Correspondent
BraunSolutions Regulatory Group
2298 Americus Blvd. East Unit 14
Clearwater, Florida 33763

Re: K233007
Trade/Device Name: PICO LEGEND 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: September 26, 2023
Received: May 13, 2024

Dear Alexander Henderson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tanisha L. Hithe -S
Digitally signed by Tanisha L. Hithe -S
Date: 2024.06.12 20:12:51 -04'00'

Tanisha Hithe
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233007

Device Name
PICO LEGEND Nd:YAG Laser System

Indications for Use *(Describe)*
The PICO LEGEND Nd:YAG Laser System is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.

-The 1064nm wavelength of the PICO LEGEND Nd:YAG Laser System is indicated for tattoo removal for dark colored tattoo inks and for multicolored tattoos containing dark colored tattoo inks on patients with all skin types (Fitzpatrick I-VI).
-The 532nm wavelength of the PICO LEGEND Nd:YAG Laser System is indicated for tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III.

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."

510(k) Summary

K233007

This summary of 510(k) is being submitted in accordance with the requirements of 21 CFR Part 807.92

Date of preparation: 6/10/2024

1. 510K Applicant / Submitter:

AMI INC.
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2. Submission Contact Person

BraunSolutions Regulatory Group
Attn: Alexander B. Henderson
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Clearwater, Florida USA 33763
Phone: 1-720-589-4939
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3. Subject Device

- Trade Name:	PICO LEGEND Nd: YAG Laser System
- Classification Name:	General & Plastic Surgery/Dermatology
- Regulation Number:	21 CFR 878.4810
- Regulation Name:	Laser Surgical Instrument For Use In General And Plastic Surgery and in Dermatology
- Regulatory Class:	II
- Product Code:	GEX

4. Predicate Device

- Trade Name:	Picocaremajesty Nd: YAG Laser System; Won Tech Co., Ltd.
- 510(k) Number:	K212127
- Regulation Number:	21 CFR 878.4810
- Regulation Name:	Laser Surgical Instrument For Use In General And Plastic Surgery and in Dermatology
- Regulatory Class:	II
- Product Code:	GEX

5. Description:

This device comprises the main body, including the optics laser generator, power supply, cooling system, operation panel, articulated arm, handpiece, foot-switch, protective goggles, power supply cord, etc. Applying a high voltage to the laser generator generates 1064nm and 532nm laser emission wavelengths. The maximum output is 500mJ.

The optical laser generator (optics), power supply, chiller, touch LCD panel, switching mode power supply, main control board, air pump, etc., are operated by a microprocessor.

The Optical Laser Generator (Optics) is comprised of Nd: YAG Rod, which is the solid laser medium, Flash lamp for optical generation, various Reflector for optical transmission, etc., and permits high voltage in flash lamp connected with power supply and operates to generate laser. After turning on the device, once the Wavelength, frequency, Frequency, Spot Size, etc., have been set, press the Foot Switch in the READY state; the laser energy will be produced and transferred through the Articulated Arm and handpiece.

6. Indications for Use

The PICO LEGEND Nd:YAG Laser System is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.

- The 1064nm wavelength of the PICO LEGEND Nd:YAG Laser System is indicated for tattoo removal for dark colored tattoo inks and multicolored tattoos containing dark colored tattoo inks on patients with all skin types (Fitzpatrick I-VI).
- The 532nm wavelength of the PICO LEGEND Nd:YAG Laser System is indicated for tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III.

7. Comparison to Predicate Device - Technical Characteristics

Determination of Substantial Equivalence [21 CFR 807.92(a)(6) and 21 CFR 807.92(b)].

Characteristics	PICO LEGEND Nd: YAG Laser System **Proposed Device**	PICOCAREMAJESTY **K212127 - Predicate Device**
Anatomical Site	Skin and subcutaneous tissue	Skin and subcutaneous tissue
Wavelength	532 or 1064nm (+/-10%)	532 or 1064nm (+/-10%)
Pulse Width	300 ps - Both Modes	532nm mode: 300-400 ps 1064nm mode: 300-400 ps
Pulse Energy	532nm mode: 50 - 250mJ (Adjustable by 25mJ) ☞ Fluence: 0.1 – 7.96 J/cm2 1064nm mode: 100 - 500mJ (Adjustable by 25mJ) ☞ Fluence: 0.1 – 15.92 J/cm2	532nm mode: 20 to 250mJ ☞Fluence: 0.1 to 7.96 J/cm2 ☞1064nm mode: 30 to 500mJ ☞Fluence: 0.2 to 16.0 J/cm2
Spot Size	2mm - 10mm (Adjustable by 1mm) - Both Modes	532nm mode: (2 to 10mm) Step: 1mm 1064nm mode: (2 to 10mm) Step: 1mm
Aiming Beam	a) Medium: Laser Diode (LD) b) Wavelength: 635nm c) Strength: Less than 5mW	a) Medium: Laser Diode (LD) b) Wavelength: 635nm c) Strength: Less than 5mW
Pulse Repetition Rate	1-10Hz (Adjustable by 1Hz)	1-10Hz (Max) – Both Modes

Laser Delivery Setup	Articulated Arm with Handpiece	Articulated Arm with Handpiece
Patient Contact Material	Aluminum (Handpiece Tip) Biocompatibility (CAS No. 7429-90-5)	Aluminum (Handpiece Tip) Biocompatibility (Cas No. 7429-90-5)

The above table shows that the technical specifications of the subject and predicate devices are comparable.

8. Performance Data (Non-clinical)

To establish the safety and efficacy of the PICO LEGEND Nd:YAG Laser System, the following evaluations were completed following standards and FDA guidance documents. All acceptance criteria were met:

Performance Testing:

-IEC 60601-1:2005/A1:2012, Medical electrical equipment Part1: General requirements for basic safety and essential performance.

-IEC 60601-1-2:2014, Medical electrical equipment Part1-2: General requirements for basic safety and essential performance.

-IEC 60601-1-6:2010/A1:2013, Medical electrical equipment Part 1-6; General requirements for safety – Collateral Standard: Usability.

-IEC 60601-2-22:2013, 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.

-Bench testing to show that the device delivers set energy parameters within specifications

Biocompatibility Testing:

-ISO 10993-5:2009 Biological evaluation of medical devices - Tests for in vitro cytotoxicity

-ISO 10993-10:2010 Biological evaluation of medical devices - Tests for skin sensitization

-ISO 10993-23:2021 Biological evaluation of medical devices – Tests for skin irritation

Software Verification and Validation Testing:

-Applicable parts of FDA Guidance Document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"

9. Clinical Testing: No clinical testing provided.

10. Conclusions:

Based on the information provided in this premarket notification, AMI INC. concludes that the PICO LEGEND Nd:YAG Laser System is substantially equivalent to the predicate device described herein regarding safety and effectiveness.