



December 21, 2023

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

Re: K233018

Trade/Device Name: PICOSECOND 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 22, 2023
Received: September 22, 2023

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,

for

Shlomit
Halachmi -S

Tanisha Hithe
Assistant Director

Digitally signed by
Shlomit Halachmi -S
Date: 2023.12.21
14:42:11 -05'00'

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)

K233018

Device Name

PICOSECOND Nd:YAG Laser System (PICO PREMIUM)

Indications for Use (Describe)

The PICOSECOND Nd:YAG Laser System (PICO PREMIUM) 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 PICOSECOND Nd:YAG Laser System (PICO PREMIUM) 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 PICOSECOND Nd:YAG Laser System (PICO PREMIUM) 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.

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510(k) Summary - K233018

December 21, 2023

This summary of 510(k) is being submitted per requirements of 21 CFR Part 807.92

1. 510K Applicant / Submitter:

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2. Submission Contact Person

BraunSolutions Regulatory Group
Attn: Alexander B. Henderson
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Phone: 1-720-589-4939
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3. Subject Device

- Trade Name:	PICOSECOND Nd: YAG Laser System
- Model:	PICO PREMIUM
- 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:

The PICOSECOND Nd: YAG Laser System (PICO PREMIUM) is comprised of the Main Body which includes an optics laser generator, power supply, cooling system, operation panel, etc., and the Articulated Arm, Handpiece, Foot Switch, Protective Goggles, Power Supply Cord, etc. and by applying high voltage to the laser generator 1064nm and 532nm wavelength and emission wavelength of the laser, the maximum output is 5 00mJ. This device is comprised of an Optical Laser Generator (Optics), power supply, chiller, touch LCD panel and switching mode power supply, main control board, air pump, etc., and is operated by microprocessor software.

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 energy.

After turning on the device, set the Wavelength, Fluence, Frequency, Spot Size, etc. to be used then press the Foot Switch in the READY state, the laser will be energized and transferred through the Articulated Arm and handpiece. A cooling system controls the febrility caused by the laser output.

6. Indications for Use

The PICOSECOND Nd: YAG Laser System (PICO PREMIUM) 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 PICOSECOND Nd: YAG Laser System (PICO PREMIUM) 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 PICOSECOND Nd: YAG Laser System (PICO PREMIUM) 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	PICOSECOND Nd: YAG Laser System (PICO PREMIUM) 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/cm ² 1064nm mode: 100 - 500mJ (Adjustable by 25mJ) ☞ Fluence: 0.1 – 15.92 J/cm ²	532nm mode: 20 to 250mJ ☞ Selectable fluence values are 0.1 to 7.96 J/cm ² at 532nm 1064nm mode: 30 to 500mJ ☞ Selectable fluence values are 0.2 to 16.0 J/cm ² . at 1064nm
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)

There are no significant differences between the PICOSECOND and the predicate device that would adversely affect the use of the product. It is substantially equivalent to this device in design, function, and technical characteristics.

8. Performance Data (Non-clinical)

To establish the safety and efficacy of the PICOSECOND Nd: YAG Laser System (PICO PREMIUM), the following evaluations were completed following standards and FDA guidance documents. All acceptance criteria were met. This product fulfills the requirements of:

- IEC 60601-1:2005/A1:2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-6:2010/A1:2013 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- IEC 60601-2-22:2007/A1:2012 - 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 (third edition) - Safety of laser products - Part 1: Equipment classification and requirements.

9. Biocompatibility Testing:

- a. ISO 10993-5:2009 Biological evaluation of medical devices - Tests for in vitro cytotoxicity
- b. ISO 10993-10:2010 Biological evaluation of medical devices - Tests for skin sensitization
- c. ISO 10993-23:2021 Biological evaluation of medical devices – Tests for skin irritation

10. Software Verification and Validation Testing:

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

11. Conclusions:

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