October 3, 2025

Jeisys Medical Incorporated
% Sanghwa Myung
Regulatory Affair Specialist
E&m
D1474, PyeongCheon Arco Tower, 230, Simin-Daro, Dongan-gu
Anyangsi, Gyeonggido 14067
Korea, South

Re: K251464
Trade/Device Name: TRI-BEAM PRO, TRI-BEAM (Nd:YAG Laser unit)
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 2, 2025
Received: September 2, 2025

Dear Sanghwa Myung:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2025.10.03 10:17:39 -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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K251464 |

Please provide the device trade name(s).

TRI-BEAM PRO, TRI-BEAM (Nd:YAG Laser unit)

Please provide your Indications for Use below.

The TRI-BEAM PRO, TRI-BEAM, Nd: YAG Laser Unit is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.

1064 Wavelength in G, TH mode:
- 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

1064nm in GN (PTP-Off) mode: - Treatment of wrinkles - Treatment of mild to moderate inflammatory acne vulgaris

532nm Wavelength (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces):
-Tattoo removal: light ink (red,tan, purple, orange, sky blue,green)
-Removal of Epidermal benign Pigmented Lesions
-Removal of Minor Vascular Lesions including but not limited to telangiectasias
-Treatment of Lentigines;
-Treatment of Cafe-Au-Lait
-Treatment of Seborrheic Keratoses
-Treatment of Post Inflammatory Hyper-Pigmentation
-Treatment of Becker's Nevi, Freckles and Nevi Spilus

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

# 510(k) Summary

## K251464

This summary of 510(k) Safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

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Primary Contact: Sanghwa Myung

**Date 510(k) summary Prepared: October 3, 2025**

**Trade Name: TRI-BEAM PRO, TRI-BEAM**

Common Name: Nd:YAG Laser Surgical Unit
Classification: II
Product Code: GEX
Regulation Numbers: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for Use In General and Plastic Surgery and In Dermatology

**Description of Device:**

TRI-BEAM PRO, Nd:YAG Laser unit in the wavelength 1064 nm, 532 nm, 585 nm, and 650 nm is intended for treatment for general dermatology. The TRI-BEAM Series, utilizing Nd:YAG laser optical energy, is based on the principle of selective photothermolysis, enabling targeted treatment of pigmented and vascular lesions, tattoos, wrinkles, acne, and other dermatologic conditions while minimizing damage to surrounding tissue. The system comprises the main unit, a color touch screen, a handpiece, and a foot switch.

**Handpiece Mode**

**PTP_ON: Single Pulse**
Laser energy is delivered to the target tissue as a single, continuous pulse.

**PTP_OFF: Dual Pulse**
One pulse is divided into two sub-pulses, delivered sequentially with a short time interval to reduce peak thermal load.

**G Mode**
Beam profile with energy concentrated at the center and gradually tapering toward the periphery, allowing focal energy delivery.

**TH Mode**
Flat-top energy distribution in which the output intensity at the center and periphery is nearly uniform, ensuring consistent tissue exposure.

**GN Mode**
Flat-top energy distribution designed to minimize strong irritation to the skin, even when applied at higher energy levels.

**Indication for use:**

The TRI-BEAM PRO, TRI-BEAM, Nd: YAG Laser Unit is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis

1064 Wavelength in G, TH mode:
- 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

1064nm in GN (PTP-Off) mode: - Treatment of wrinkles - Treatment of mild to moderate inflammatory acne vulgaris

532nm Wavelength (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces):
-Tattoo removal: light ink (red,tan, purple, orange, sky blue,green)
-Removal of Epidermal benign Pigmented Lesions
-Removal of Minor Vascular Lesions including but not limited to telangiectasias
-Treatment of Lentigines;
-Treatment of Cafe-Au-Lait
-Treatment of Seborrheic Keratoses
-Treatment of Post Inflammatory Hyper-Pigmentation
-Treatment of Becker's Nevi, Freckles and Nevi Spilus

**Predicate Device:**

| | |
|---|---|
| Predicate Devices 1 | K241527<br>Applicant: Wontech Co., Ltd<br>Trade/Device Name: Pastelle PRO<br>Regulation Number: 21 CFR 878.4810<br>Regulation Name: Laser surgical instrument for use in general and plastic surgery and in Dermatology<br>Regulatory Class: Class II<br>Product Code: GEX |

**Substantial Equivalence:**
Comparison table is as follows.

**Table 1: Substantial equivalence comparison**

| | Proposed Device | Predicate Device | **Comparison Comment** |
|---|---|---|---|
| 510(k) Number | Pending | K241527 | - |
| Manufacturer | Jeisys Medical Inc | Wontech Co., Ltd | - |

| | | | |
|---|---|---|---|
| Trade/Device Name | TRI-BEAM PRO, TRI-BEAM | Pastelle PRO | - |
| Classification Name | Laser surgical instrument for use in general and plastic surgery and in Dermatology | Laser surgical instrument for use in general and plastic surgery and in Dermatology | - |
| Indication for use | The TRI-BEAM PRO, TRI-BEAM, Nd: YAG Laser Unit is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis. | The Pastelle Pro system is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis. | Same |
| | 1064 nm in G, TH mode - 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 wrinkles - Treatment of melasma<br><br>1064nm in GN (PTP-Off) mode: - Treatment of wrinkles - Treatment of mild to moderate inflammatory acne vulgaris | 1064nm in nanosecond mode, including microbeam handpieces:<br>- 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 wrinkles - Treatment of melasma<br><br>1064nm in Genesis (long-pulse) mode: - Treatment of wrinkles - Treatment of mild to moderate inflammatory acne vulgaris | Same |
| | 532nm Wavelength (nominal delivered energy of 585 nm and 650 nm with optional dye<br><br>handpieces):<br><br>-Tattoo removal: light ink (red,tan, purple, orange, sky blue,green)<br><br>-Removal of Epidermal benign Pigmented Lesions<br><br>-Removal of Minor Vascular Lesions | 532nm in nanosecond mode, including microbeam handpieces (nominal delivered energy of 595 nm and 660 nm with optional dye handpieces): - 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 - Skin resurfacing procedures for the treatment of acne scars | Same |

| | | | |
|---|---|---|---|
| | including but not limited to telangiectasias<br><br>-Treatment of Lentigines;<br><br>-Treatment of Cafe-Au-Lait<br><br>-Treatment of Seborrheic Keratoses<br><br>-Treatment of Post Inflammatory Hyper-Pigmentation<br><br>-Treatment of Becker's Nevi, Freckles and Nevi Spilus | and wrinkles - Treatment of Lentigines - Treatment of Café-au-Lait - Treatment of Seborrheic Keratoses - Treatment of Post Inflammatory Hyperpigmentation - Treatment of Becker's Nevi, Freckles, and Nevi spilus | |
| Laser Medium | Nd:YAG laser | Nd:YAG laser | Same |
| Wavelength | 1064nm, 532nm, 585nm, 650nm | 1064nm, 532nm, 585nm, 650nm | Same |
| Duration (Pulse Width) | 1064nm<br>5-10ns (G, TH mode)<br>300µs (GN mode)<br>532nm : 5-10ns (TH mode)<br>585nm : 5-10ns (TH mode)<br>650nm: 5-10ns (TH mode) | 532nm/1064nm mode: 5ns~12ns<br>1064 PTP/Triple/2X PTP: Up to 20ns<br>Genesis mode: 80~300µs | Substantial Equivalence |
| Pulse Energy (max) | 1064 GN/PTP OFF mode: 3500 mJ<br>1064 TH/PTP ON mode: 1600 mJ<br>1064 TH/PTP OFF mode: 1200 mJ<br>1064 G/PTP OFF mode: 1500 mJ<br>532 / PTP OFF mode: 500 mJ<br>585 / PTP OFF mode: 250 mJ<br>650 / PTP OFF mode: 150 mJ | Genesis mode: 100 ~ 5,000 mJ<br>1064 nm mode: 50 ~ 1,200 mJ<br>1064 nm PTP mode: 600 ~ 2,000 mJ<br>1064 nm Triple mode: 1,000 ~ 1400 mJ<br>1064 nm 2x PTP mode: 1,000 ~ 1400 mJ<br>532 nm mode: 30 ~ 500 mJ<br>1064 nm DOE mode: 60 ~ 900 mJ<br>595 nm Dye mode: 30 ~ 250 mJ 660 nm Dye mode: 30 ~ 150 mJ | Substantial Equivalence |
| Spot Size(mm) | Zoom: 2~10mm<br>Collimation: 7mm<br>1064 nm: 4.5 x 4.5mm$^2$<br>532 nm: 5 x5 mm$^2$<br>Dye: 2mm | Zoom: 2mm ~ 10mm<br>Collimation: 7mm<br>MLA: 3mm ~ 8mm<br>DOE: 5mm x 5mm ~ 7mm x 7mm<br>Dye: 3mm | Different #1 |
| Repetition rate | 1064 nm GN Mode: 1 ~ 10 Hz<br>1064 nm G mode: 1 ~ 10Hz<br>1064 nm TH PTP on mode, PTP off mode: 1 ~ | Genesis mode: 1 ~ 10 Hz<br>1064 nm mode: 1 ~ 10 Hz<br>1064 nm PTP mode: 1 ~ 10 Hz<br>1064 nm Tripple mode: 1 ~ 10 Hz | Different #2 |

| | | | |
|---|---|---|---|
| | 10Hz<br>532nm : 1 ~ 10Hz<br>585nm: 1 ~ 2 Hz<br>650nm: 1 ~ 2 Hz | 1064 nm 2x PTP mode: 1 ~ 10 Hz<br>532 nm mode: 1 ~ 10 Hz<br>1064 nm DOE mode: 1 ~ 10<br>Hz<br>595 nm Dye mode: 1 ~ 5 Hz<br>660 nm Dye mode: 1 ~ 2 Hz | |

**Discussion**
The subject device and predicate device have some difference characteristics such as pulse energy, spot size, repetition rate that do not raise different questions of safety and effectiveness. The Subject device technical characteristics are within the range of the predicate device. The subject device and predicate device have some difference characteristics that do not raise different questions of safety and effectiveness. To support this, we conducted related pre-clinical test.

**Non-clinical Performance Data**:

-. Basic safety and essential performance of device was evaluated in accordance with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020

-. Effect to the device by electromagnetic disturbances is evaluated in accordance with the FDA-recognized consensus standard, IEC 60601-1-2:2014.

-. IEC 60601-2-22 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 Ed. 3.0 (2014) Safety of laser products – Part 1: Equipment classification and requirements

-. General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability is evaluated in accordance with the FDA-recognized consensus standard, IEC 60601-1-6:2013.

-. The software is verified and validated in accordance with its moderate level of concern. Software life cycle processes are evaluated according to the FDA-recognized consensus standard, IEC 62304:2006.

-. Application of usability engineering to medical devices is evaluated in accordance with IEC 62366:2008 based on Human Factor Engineering

-. Biocompatibility is documented in the reference of ISO 10993-1:2009, ISO 10993-5:2009, and 10993-10:2010.

**Bench testing**

Jeisys Medical Inc conducted bench testing to assure that TRI-BEAM PRO, TRI-BEAM operates safely and within the predefined design specifications.

**Risk Management**

A risk analysis was conducted based on ISO 14971:2019 Medical devices – Application of risk management to medical devices

**Clinical Data:**

No clinical performance testing was performed.

**Conclusion**

Subject device is substantially equivalent to its predicate devices with same indication for use and technological characteristics. The non-clinical data for proposed device, including biocompatibility, bench testing, hardware, and software documentation shows that the device should perform as intended in the specified use. In addition, the Electromagnetic Compatibility and Electrical Safety testing shows that the device is safe to use and meets require. There are no significant differences between Subject device 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 standards. In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification that we conclude that substantially equivalent with predicate device K241527.