March 11, 2026

CAO Group, Inc.
Robert Larsen
Regulatory Affairs Manager
4628 W. Skyhawk Dr.
West Jordan, Utah 84084

Re: K254197
Trade/Device Name: Picasso Pro Diode Laser (002-00460)
Regulation Number: 21 CFR 878.4810, 872.6475
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX, NVK, EEG
Dated: December 23, 2025
Received: December 23, 2025

Dear Robert Larsen:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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: 2026.03.11 23:22:03 -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)*
K254197

Device Name
Picasso Pro Diode Laser (002-00460)

Indications for Use *(Describe)*
The Picasso Pro Diode Laser is indicated for dentistry and oral soft tissue procedures of:
1) The removal of lesions, excision, incision, vaporization, ablation, hemostasis, and photocoagulation on soft tissue including abscess treatment, contouring, curettage, sulcular debridement, pulp extirpation, pulpotomy, frenectomy, gingivectomy, troughing, and removal of inflamed edematous tissue.
2) Temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local blood circulation, and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions;
3) Light activation of bleaching materials for teeth whitening and laser-assisted whitening/bleaching of teeth.

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 – K254197

Applicant Information:

Company Name: CAO Group, Inc.
Company Address: 4628 West Skyhawk Drive
West Jordan, Utah 84084 U.S.A.
Company Phone: 1-801-256-9282
Company Fax: 1-801-256-9287

Contact Person: Robert K. Larsen

Preparation Date: March 6, 2026

Device Name:

Trade Name:	Picasso Pro Diode Laser
Common Name:	Powered Laser Surgical Instrument
Product Code:	GEX, NVK, EEG
Regulation:	878.4810, 872.6475
Product Classification:	Class II
510(k) Number:	K254197

Legally Marketed Predicate Device for Substantial Equivalence:

Precise SHP Diode Laser, manufactured by CAO Group, Inc. (K181601)

Legally Marketed Reference Device for Substantial Equivalence:

Picasso Plus, Picasso Lite Plus, manufactured by AMD Group, LLC (K152939)

NeoLas 810 Soft Tissue Laser, manufactured by Sheaumann Laser, Inc. (K150664)

Description of Submitted Device:

The Picasso Pro Diode Laser is a device for delivering laser energy to human oral and dental soft tissue for a variety of surgical procedures and treatments. This energy is generated by solid-state diodes, which provide a consistent and reliable generation of laser energy at 810 ± 20nm for a maximum of 7 watts of energy output. The laser energy is delivered to the surgical site by means of an optical fiber system, which allows for the safe transmission of laser energy to the site without creating undue risk to the patient or operatory staff by errant or collateral laser emissions. The device features some user definable settings, including a switchable 630nm aiming beam, adjustable power output for both the working beam and aiming beam, and continuous delivery or pulse delivery options. The working end of the delivery fiber is contained within a metal handpiece with an attached disposable single-use tip for surgical procedures. This handpiece system is incorporated into the device. The activation of the working beam diodes is completed by use of a foot-actuated switch.

Indications for Use of the Submitted Device:

The Picasso Pro Diode Laser is indicated for dentistry and oral soft tissue procedures of:

1) The removal of lesions, excision, incision, vaporization, ablation, hemostasis, and photocoagulation on soft tissue including abscess treatment, contouring, curettage, sulcular debridement, pulp extirpation, pulpotomy, frenectomy, gingivectomy, troughing, and removal of inflamed edematous tissue.
2) Temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local blood circulation, and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions;
3) Light activation of bleaching materials for teeth whitening and laser-assisted whitening/bleaching of teeth.

Rationale for Substantial Equivalence:

The submitted device is identical in materials and construction of the overall laser unit as the predicate Precise SHP Diode Laser. The submitted device incorporates the exact same handpiece design, handpiece materials of construction, and single use fiber tips as the reference Picasso Plus Diode Laser. The submitted device features the exact same indications for use as the predicate Precise SHP Diode Laser, with the addition of an indication of pulp extirpation that is featured in the reference NeoLas 810 Soft Tissue Laser. The submitted device is used by the same licensed dental professional, in the same dental operatory environment, with the same operating principle, same laser energy source at the same wavelength and same output intensity, and the same energy delivery method as the cited predicate devices. The submitted device uses the same control principle, same software architecture, similar user input-output interface, and same hardware control mechanisms as the predicate Precise SHP Diode Laser. The submitted device was designed by and will be manufactured by the same manufacturer as the predicate Precise SHP Diode Laser.

Present Submission (pending)	*Predicate Device (K181601)*	*Predicate Device (K150664)*	*Reference Device (K152939)*
DEVICE CHARACTERISTICS/SPECIFICATIONS			
Working Beam Output Wavelength: 810±10nm	Working Beam Output Wavelength: 810±10nm	Working Beam Output Wavelength: 808±10nm	Working Beam Output Wavelength: 810±10nm
Working Beam Output Power Range: 0.5 - 7.0 watts	Working Beam Output Power Range: 0.5 - 3.0 watts	Working Beam Output Power Range: Up to 2.5 watts	Working Beam Output Power Range: 0.5 -7.0 watts
Aiming Beam Output Wavelength: 650±20nm	Aiming Beam Output Wavelength: 650±20nm	Aiming Beam Output Wavelength: Not Available	Aiming Beam Output Wavelength: 650±20nm
Aiming Beam Output Power Range: < 3 milliwatts	Aiming Beam Output Power Range: < 3 milliwatts	Aiming Beam Output Power Range: Not Available	Aiming Beam Output Power Range: < 3 milliwatts
Working Beam Activation: Wireless	Working Beam Activation: Wireless		

Present Submission (pending)	*Predicate Device (K181601)*	*Predicate Device (K150664)*	*Reference Device (K152939)*
momentary foot switch Emission Frequency: Continuous or Pulsed Electrical Power Input (Power Supply): 100-240VAC switchable, 47-63Hz, 1.5A Main Unit Dimensions: 10" x 7.5" x 5.5" Main Unit Weight: 4 lbs. Factory-defined Presets: Yes Laser Stop Button: Yes Patient-contacting Materials: – Handpiece: Anodized aluminum – Single-use Laser Fiber Tip: Polypropylene housing, Type 316 stainless steel canula, with silica glass optical fiber protruding from the canula Single-use Articles: Single-Use Laser Fiber Tip; Sterilization of Articles: – Single-Use Tip: Immersion in approved liquid chemical sterilant, then rinsed with clean water	momentary foot switch Emission Frequency: Continuous or Pulsed Electrical Power Input (Power Supply): 100-240VAC switchable, 47-63Hz, 1.5A Main Unit Dimensions: 5.5" x 4.5" x 4.5" Main Unit Weight: 1.25 lbs. Factory-defined Presets: Yes Laser Stop Button: Yes Patient-contacting Materials: – Handpiece: Anodized aluminum – Single-use Laser Fiber Tip: ABS plastic housing, with silica glass optical fiber protruding from the canula Single-use Articles: Single-Use Laser Fiber Tip; Sterilization of Articles: - Single-Use Tip: Immersion in approved liquid chemical sterilant, then rinsed with clean water	Working Beam Activation: Not Available Emission Frequency: Not Available Electrical Power Input (Power Supply): Not Available Unit Dimensions: Not Available Unit Weight: Not Available Factory-defined Presets: Not Available Laser Stop Button: Not Available Patient-contacting Materials: – Not Available Single-use Articles: Not Available	Working Beam Activation: Wireless momentary foot switch Emission Frequency: Continuous or Pulsed Electrical Power Input (Power Supply): 100-240VAC switchable, 47-63Hz, 1.5A Main Unit Dimensions: 9" x 6.25" x 6" Main Unit Weight: 2 lbs. Factory-defined Presets: Yes Laser Stop Button: Yes Patient-contacting Materials: – Handpiece: Anodized aluminum – Single-use Laser Fiber Tip: Polypropylene housing, Type 316 stainless steel canula, with silica glass optical fiber protruding

Present Submission (pending)	*Predicate Device (K181601)*	*Predicate Device (K150664)*	*Reference Device (K152939)*
		Sterilization of Articles: Not Available	from the canula Single-use Articles: Single-Use Laser Fiber Tip; Sterilization of Articles: - Single-Use Tip: Immersion in approved liquid chemical sterilant, then rinsed with clean water

Key Differences:
The submitted device is identical in design, materials, and construction to the Picasso Plus reference device, except for the detachable display and the therapy and whitening handpiece attachments which are identical in materials to the Precise SHP predicate device.

Information on the NeoLas 810 reference device could not be obtained, relative to the configuration or components of the device in order to make a determination of similarities or differences. It should be noted that the submitted device and the reference NeoLas 810 device share identical laser source and laser wavelength, and statements in the 510(k) clearance letter for this reference device suggest a similar range of output power for the infrared laser beam.

The submitted device differs from the Precise SHP predicate device and Picasso Plus reference device with regards to physical dimensions, and the user interface for the current device being larger than was utilized for the Precise SHP predicate device.

INDICATIONS FOR USE			
The Picasso Pro Diode Laser is indicated for dentistry and oral soft tissue procedures of: 1) The removal of lesions, excision, incision, vaporization, ablation, hemostasis, and photocoagulation on soft tissue including abscess treatment,	The Precise SHP Diode Laser is indicated for dentistry and oral soft tissue procedures of: 1) The removal of lesions, excision, incision, vaporization, ablation, hemostasis, and photocoagulation on soft tissue including abscess treatment,	The NeoLas 810nm Soft Tissue laser and its accessories are intended for use on adult and pediatric patients in dentistry, dermatology and other surgical areas in the following procedures:	The Picasso Plus /Picasso Lite Plus is generally indicated for incision, excision, vaporization, ablation and coagulation of oral soft tissues including the following: - Gingival troughing for crown impression

Present Submission (pending)	*Predicate Device (K181601)*	*Predicate Device (K150664)*	*Reference Device (K152939)*
contouring, curettage, sulcular debridement, pulpotomy, pulp extirpation frenectomy, gingivectomy, troughing, and removal of inflamed edematous tissue. 2) Temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local blood circulation, and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions; 3) Light activation of bleaching materials for teeth whitening and laser-assisted whitening/bleaching of teeth.	contouring, curettage, sulcular debridement, pulpotomy, frenectomy, gingivectomy, troughing, and removal of inflamed edematous tissue. 2) Temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local blood circulation, and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions; 3) Light activation of bleaching materials for teeth whitening and laser-assisted whitening/bleaching of teeth.	Soft Tissue Indications including Pulpal Tissues* Incision, excision, vaporization, ablation and coagulation or oral soft tissues, including: - Excisional and incisional biopsies - Exposure of unerupted teeth - Fibroma removal - Flap preparation—incision of soft tissue to prepare a flap and expose the bone. - Flap preparation—incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions) - Frenectomy and frenotomy - Gingival troughing for crown impressions - Gingivectomy - Gingivoplasty - Gingival incision and excision	- Gingivectomy - Gingivoplasty - Gingival incision and excision - Hemostasis and coagulation - Excisional and incisional biopsies - Exposure of unerupted teeth - Fibroma removal - Frenectomy and frenotomy - Implant recovery - Incision and drainage of abscess - Leukoplakia - Operculectomy - Oral papillectomies - Pulpotomy - Pulpotomy as an adjunct to root canal therapy - Reduction of gingival hypertrophy - Soft tissue crown lengthening - Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa - Vestibuloplasty Laser Periodontal Procedures, including: - Sulcular debridement (curettage, removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including: gingival index,

Present Submission (pending)	*Predicate Device (K181601)*	*Predicate Device (K150664)*	*Reference Device (K152939)*
		- Hemostasis and coagulation - Implant recovery - Incision and drainage of abscesses - Laser soft tissue curettage of the post-extraction tooth sockets and the periapical area during apical surgery - Leukoplakia - Operculectomy - Oral papillectomies - Pulpotomy - Pulp extirpation - Pulpotomy as an adjunct to root canal therapy - Reduction of gingival hypertrophy - Removal of pathological tissues (i.e. cysts, neoplasm or abscess) and hyperplastic tissues (i.e. granulation tissue) from around the apex - Root canal debridement and cleaning - Soft tissue crown lengthening - Treatment of canker sores, herpetic and	gingival bleeding index, probe depth, attachment loss and tooth mobility) - Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium - Picasso assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium).

Present Submission (pending)	*Predicate Device (K181601)*	*Predicate Device (K150664)*	*Reference Device (K152939)*
		aphthous ulcer of the oral mucosa - Vestibuloplasty NOTE: Any tissue growth (i.e. cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation	

Key Differences:
The indications for use of the submitted device are exactly identical to those of the Precise SHP predicate device except that the submitted device adds a procedure of 'pulp extirpation', as found in the indications for use of the NeoLas 2 reference device. The submitted device does not borrow from or make any additional comparisons to the indications for use of either the NeoLas 2 or the Picasso Plus reference devices.

Performance Data:
This device has been validated and certified compliant to the following recognized standards:

- 60601-1 Edition 3.2 2020-08. Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- 60601-1-6 Edition 3.2 2020-07. Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- 60601-2-22 Edition 3.1 2012-10. Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
- 60825-1 Edition 2.0 2007-03. Safety of laser products - Part 1: Equipment classification, and requirements.
- 62366-1 Edition 1.1 2020-06. Medical devices - Part 1: Application of usability engineering to medical devices.

Software verification and validation testing consistent with basic documentation were conducted in accordance with the recommendations provided in the FDA guidance document "Content of Premarket Submissions for Device Software Functions".

The optical fibers, handpieces, and single-use tips utilized in the Picasso Pro, in its final finished form, are identical to the same components of optical fibers, handpieces, and single-use tips utilized in the predicate

device, the “Picasso Plus” in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents). The predicate device was cleared under K152939. Therefore, based on this information, no biocompatibility testing was needed to support substantial equivalence of this device.

Considering the similarities in design, materials, construction, user profile, environment of use, and indications for use between the submitted device and the predicate and reference devices, as indicated above and throughout the submission, no performance testing or comparison was conducted.

Conclusion:

The Picasso Pro Diode Laser is substantially equivalent to the listed predicate devices without raising any new issues of safety or effectiveness. This device shares a very similar intended use, and similar principle of operation. Performance data supports that the device is capable of achieving the intended effect without raising substantial concerns for safety.