



March 10, 2026

Azena Medical, LLC
% Dave Yungvirt
CEO
Third Party Review Group, LLC
7 Giralda Farms, Suite 120a
Madison, New Jersey 07940

Re: K260765

Trade/Device Name: Gemini NOVA 810+980 Soft Tissue Laser
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: NVK, GEX, ILY
Dated: March 8, 2026
Received: March 9, 2026

Dear Dave Yungvirt:

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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director

DHT1B: Division of Dental and
ENT Devices

OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K260765

Device Name
Gemini NOVA 810+980 Soft Tissue Laser

Indications for Use (Describe)
Dental Soft Tissue Indications

Incision, excision, vaporization, ablation and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- 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
- Treatment of aphthous ulcers.
- Vestibuloplasty
- Tissue retraction for impression
- Lesion (tumor) removal.

Laser Periodontal Procedures.

- Laser soft tissue curettage.
- Laser removal of diseased, Infected, Inflamed and necrosed soft tissue within the periodontal pocket.
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium.
- Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
- Reduction of bacterial level (decontamination) and inflammation

Pain therapy

• Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain, the temporary increase in local blood circulation; the temporary relaxation of muscle.

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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510(k) Summary

Submitter Information (21 CFR 807.92)

Azena Medical, LLC
1777 Botelho Drive, Suite 100, Walnut Creek, CA 94596 USA
Contact Person: Lindsay Tilton
Telephone: (925) 699-9091
Date Prepared: March 4, 2026

Device Trade Name: Gemini Nova 810 + 980 Soft Tissue Laser

Common Name: Dental Laser, Soft-Tissue, Powered

Classification: Class II

Regulation: 21 CFR 878.4810

Product Codes: NVK (primary); GEX; ILY

Predicate Device

Gemini 2 (Gemini EVO) 810 + 980 Soft Tissue Laser (K210350)

Indications for Use

Dental Soft Tissue Indications

Incision, excision, vaporization, ablation and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indications:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- 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
- Treatment of aphthous ulcers.
- Vestibuloplasty
- Tissue retraction for impression
- Lesion (tumor) removal.

Laser Periodontal Procedures

- Laser soft tissue curettage.
- Laser removal of diseased, Infected, Inflamed and necrosed soft tissue within the periodontal pocket.
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium.
- Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
- Reduction of bacterial level (decontamination) and inflammation

Pain therapy

- Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain, the temporary increase in local blood circulation; the temporary relaxation of muscle.

Device Description

The Gemini Nova 810 + 980 Soft Tissue Laser is a dual-wavelength diode laser system delivering 810 nm and 980 nm laser energy for oral soft-tissue procedures. Laser energy is delivered through fiber-optic disposable tips or photobiomodulation (PBM) adapters. The system includes a base unit, wand, wireless foot pedal, and rechargeable battery packs.

Comparison of Technological Characteristics

Feature	Gemini Nova	Predicate Device (Gemini 2 K210350)
Laser Type	GaAlAs diode	GaAlAs diode
Wavelengths	810 ±10 nm, 980 ±10 nm	810 ±10 nm, 980 ±10 nm
Peak Power	20 W	150 W
Average Power	0.1 – 2.0 W	0.1 – 2.0 W
Energy Delivery	Fiber tips and PBM adapters	Fiber tips and PBM adapters

Feature	Gemini Nova	Predicate Device (Gemini 2 K210350)
Activation	Wireless Foot Switch	Wireless Foot Switch
Accessories	Disposable fiber tips. Safety eyewear; Aluminum hand piece; 25mm PBM Adapter with spacers, 7mm and 3 mm intraoral PBM adapters, Wand battery (2), Barrier sleeves (10 ea. fiber tips, 5 ea. 3mm and 5 ea. 7mm) and the light adapters for the PBM tips (5)	Disposable fiber tips; Safety eyewear; Aluminum hand piece; 25mm PBM Adapter with spacers, 7mm and 3 mm intraoral PBM adapters
Power Source	Internal lithium-ion battery packs, AC Adapter	Battery pack and AC adapter
User Interface	Capacitive touchscreen	Electroluminescent display
Connectivity	BLE wireless architecture connecting wand (cordless), base, and foot pedal	BLE wireless architecture connecting unit (corded handpiece attached to base) and foot pedal
Reprocessing	Cleaning and Low-Intermediate disinfection validated (Caviwipes) due to not being able to steam sterilize handpiece. Steam sterilization validated for 3mm and 7mm PBM adapters	Cleaning and Steam sterilization validated for handpiece shell and 3mm/7mm PBM adapters
Intended Environment	Dental clinical environments	Dental clinical environments

Rationale for Technological Differences

Peak Pulse Power

The Gemini NOVA has a lower maximum peak pulse power (20 W) than the predicate Gemini 2 (150 W); however, both devices operate within the same average power range (0.1–2.0 W), which primarily determines clinical performance. Bench testing confirmed accurate power output, and this difference does not raise new questions of safety or effectiveness.

Accessories

The Gemini NOVA accessory set includes disposable fiber tips, safety eyewear, an aluminum handpiece, PBM light adapters (3 mm, 7 mm, and 25 mm with spacer), barrier sleeves, and lithium-ion battery packs for the cordless wand. In the predicate Gemini 2 system, photobiomodulation (PBM) energy is delivered through an external optical fiber assembly, while in the Gemini NOVA the external fiber cord has been eliminated as part

of the cordless wand design and PBM light adapters interface directly with the integrated fiber ferrule to provide equivalent beam expansion, spot size, and energy distribution at the tissue interface. The adapters are manufactured from the same optical fiber material used in the predicate device and do not alter wavelength, output power, pulse characteristics, or average power; therefore, these differences do not raise new questions of safety or effectiveness.

Power Source

The Gemini NOVA utilizes rechargeable lithium-ion battery packs to support cordless operation. Battery safety testing confirmed compliance with applicable standards, and this difference does not raise new questions of safety or effectiveness.

User Interface / Display

The Gemini NOVA uses a 5”×5” capacitive touchscreen, while the predicate device uses an electroluminescent display with capacitive touch controls. Because both devices use the same touch-control method and usability testing confirmed effective operation, this difference does not raise new questions of safety or effectiveness.

Connectivity

The Gemini NOVA incorporates Bluetooth Low Energy communication between system components, whereas the predicate uses a different connectivity configuration. This functionality only supports system control and does not affect laser energy delivery, and therefore does not raise new questions of safety or effectiveness.

Reprocessing Method

The Gemini NOVA uses validated cleaning and intermediate-level disinfection procedures for reusable components except for the 3mm and 7mm PBM adapters, which still can be steam sterilized. The predicate device uses steam sterilization. Reprocessing validation confirmed effective cleaning and microbial reduction, and this difference does not raise new questions of safety or effectiveness.

Performance Data

The following non-clinical testing was conducted to support substantial equivalence of the Gemini Nova system.

Electrical Safety

Electrical safety testing was performed to demonstrate compliance with IEC 60601-1 requirements for medical electrical equipment. Testing confirmed the device met requirements for basic safety and essential performance.

Electromagnetic Compatibility (EMC)

Electromagnetic compatibility testing was conducted according to IEC 60601-1-2:2014 + A1:2020. Testing evaluated both emissions and immunity performance and confirmed that the device meets applicable EMC requirements.

Radio Frequency Emissions

Testing was conducted in accordance with FCC Part 15 Subpart B and ICES-003 for unintentional radiators. The Gemini Nova system met Class A limits for conducted and radiated emissions.

Wireless Coexistence

Wireless communication functions were evaluated for compliance with applicable RF emission and immunity standards including ETSI EN 301 489-1 and ETSI EN 301 489-17. Testing demonstrated compliant wireless performance.

Battery Safety Testing

Rechargeable lithium-ion battery packs used in the system were evaluated in accordance with IEC 62133-2:2017 safety requirements.

The battery packs met all applicable safety requirements.

Laser Performance

Laser output characteristics were evaluated in accordance with IEC 60601-2-22 requirements for medical laser equipment and IEC 60825-1 for laser product safety, including classification, labeling, and user protection requirements. Testing verified that the laser output power remained within $\pm 20\%$ of the selected setting and confirmed compliance with applicable safety requirements for Class IV medical laser systems.

Biocompatibility

Biocompatibility testing of patient-contacting components was conducted in accordance with ISO 10993 standards. Testing included:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation / intracutaneous reactivity (ISO 10993-10)

Test results demonstrated that the materials were non-cytotoxic, non-sensitizing, and non-irritating.

Reprocessing Validation

Cleaning and intermediate-level disinfection procedures were validated to confirm effective removal of biological soil and reduction of microbial contamination on reusable components.

Software Verification and Validation/Cybersecurity

Software development and verification activities were conducted in accordance with IEC 62304 lifecycle processes, and the software was classified as Moderate Level of Concern. Verification and validation testing confirmed correct system operation, and cybersecurity controls—including user authentication, encrypted wireless communication, and secure software update mechanisms—were implemented to support the confidentiality, integrity, and availability of the system.

Bench Testing

Nonclinical bench performance testing was conducted to verify that the Gemini NOVA 810+980 Soft Tissue Laser meets its design specifications and performs safely and effectively under intended use conditions. Testing evaluated laser output accuracy and stability, PBM optical delivery performance, mechanical durability and battery cycling performance, under worst-case and extended-use conditions. Results demonstrated that laser output remained within $\pm 20\%$ of stated values, optical performance and spot size were consistent with specifications, and the device maintained mechanical and electrical integrity following simulated lifetime use. All testing met predefined acceptance criteria and supports substantial equivalence to the predicate device.

Clinical Data

No clinical studies were conducted or submitted as part of this 510(k) submission.

Clinical data were not required to demonstrate substantial equivalence because the subject device has the same intended use and similar technological characteristics as the predicate device.

Non-clinical testing and bench testing were sufficient to support substantial equivalence.

Conclusion

The Gemini Nova 810 + 980 Soft Tissue Laser is substantially equivalent to the predicate device and does not raise new questions of safety or effectiveness. To the best of the manufacturer's knowledge, the predicate device has not been subject to any safety-related recalls.