November 18, 2021

Azena Medical, LLC
Lindsay Tilton
Regulatory and Quality Affairs Manager
3021 Citrus Circle Suite 180
Walnut Creek, California 94598

Re: K210350
Trade/Device Name: Gemini 2 810+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: October 19, 2021
Received: October 21, 2021

Dear Lindsay Tilton:

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 (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 located 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.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 Michael E. Adjodha, M.ChE.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210350

Device Name
Gemini 2 810 +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.

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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

K210350

Traditional 510(k) Premarket Notification

Submitter:
Azena Medical, LLC
3021 Citrus Cir Ste 180,
Walnut Creek, CA 94598
Phone: (800) 466–5273

Regulatory Authority:

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990, 21 CFR 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared:

Submitter:	Azena Medical, LLC 3021 Citrus Cir Ste 180, Walnut Creek, CA 94598
Contact Person:	Lindsay Tilton Regulatory & Quality Affairs Manager Phone: 800-466-5273 Email: ltilton@azenamedical.com
Date of Preparation:	November 17, 2021

2. Name of device, including the trade name and classification name:

Trade Name:	Gemini 2 810+980 Soft Tissue Laser
Common Name(s):	Laser, dental soft tissue, Powered laser surgical instrument, Infrared lamp
Classification Name(s):	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Number:	***21 CFR 878.4810***

Device Class: Class II

Primary Product Code: NVK
Additional Product Code: GEX,ILY

Classification Panel: General dental and Plastic Surgery & Others
Physical Medicine Therapeutic Devices

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Primary Predicate Device:

Company: **Azena Medical, LLC**
Device: **Gemini 810+980 Diode laser**
510(k): **K192617**
Date Cleared: **February 20, 2020**

Reference Predicate Device:

Company: **Biolase Technology, Inc.**
Device: **Epic Pro Diode Laser System**
510(k): **K163128**
Date Cleared: **January 11, 2017**

4. A description of the device that is the subject of the 510(k), including an explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):

The Gemini 2 810+980 Soft Tissue Laser is an 810+980nm soft tissue laser intended for the incision, excision, ablation, vaporization, hemostasis, and treatment of oral soft tissue and for pain relief using Photobiomodulation. The Gemini 2 810+980 Soft Tissue Laser operates at a wavelength of 810±10nm or at 980±10nm or a combination of both 810+980nm, with a maximum average power output of 2.0 watts ± 20%. The system also contains a 2mW, 650nm laser diode coupled to the same fiber optic cable to produce a red aiming light for the infrared laser beams.

The laser energy is generated in an internal laser module and is then channeled through a flexible optical fiber that is permanently connected to a hand piece. Single-use disposable tips, or Photobiomodulation (PBM) adapters, become the laser aperture of the device when they are optically coupled to the fiber in the hand piece. The disposable tips and

Photobiomodulation tips are interchangeable and provide a method of delivering laser energy to the target area.

The laser unit is comprised of a molded plastic housing that contains: the laser module, main PCB with integrated MCU and laser controller, an electroluminescent display connected to an interface PCB, a touch sensitive graphic user interface with status indicators, and a rechargeable lithium-ion battery.

The handpiece used by the practitioner consists of a cylindrical body of anodized aluminum which encloses the optics that transmit the laser energy to the disposable fiber tip or PBM adapters. The red aiming light is emitted directly from the aperture of the laser attached to the hand piece. Additionally, the handpiece illuminates the target work area with bright white LED lights during procedures through the translucent disposable tips.

The wireless footswitch provides hands-free laser activation. The switch utilized high band Bluetooth technology to wirelessly control the initiation and termination of laser power from the laser aperture. Haptic feedback is also incorporated into the foot pedal to provide a vibration upon laser activation which can be adjusted from low to medium, or high.

The single-use disposable fiber tip includes a translucent plastic tip body, stainless steel tube and a 400-micron polished optical fiber. The Gemini 2 810 + 980 Soft Tissue Laser was designed to utilize the same disposable tip as the Gemini 810+980 Soft Tissue Laser, previously cleared by FDA (K192617).

The PBM adapters are accessory attachments for the Gemini 2 810 + 980 Soft Tissue Laser which expand the diameter of the laser beams spot size to 25mm, 3mm or 7mm. The lager diameter laser beam is used for Photobiomodulation indications such as pain management. The PBM adapters are designed to be held in a fixed location for the duration of the treatment. The 25mm adapter is only intended for extraoral use directly on intact skin and is designed at a diameter for larger work areas. Single-use disposable spacers are intended to be used with the 25mm adapter to limit the risk of cross contamination between patients. Due to the extraoral use, and disposable spacers, the 25mm PBM adapter is not to be steam sterilized. The 3mm and 7mm PBM tips are intended to be used intraorally and are designed at an l angle for reaching the back of the mouth. Steam sterilization and cleaning are required for both the 3mm and 7mm PBM adapters before each use. Non-clinical testing was conducted on the 3mm and 7mm adapters to test that the adapters increased the intra oral tissue temperature to the FDA guidelines for the ILY product code. The results showed that even in the intraoral environment, the efficacy of the adapters was met and showed substantial equivalence to the previously cleared device. In addition, non-clinical testing was also conducted with the use of an FDA cleared barrier sleeve over the 3mm and 7mm Intra Oral adapters. The results show that the use of the sleeve did not affect the efficacy of the product.

The laser unit is controlled by a Main Control Unit (MCU) processor that is integrated into the main PCB. The PCB contains the software and hardware which regulates voltages and current and controls all the other functions and safety features. The PCB may be powered by either lithium-ion battery pack, or the included AC power supply. The PCB was designed to allow the power supply to provide power to the unit while simultaneously charging the battery pack.

The Gemini 2 810+980 Soft Tissue Laser utilizes non-volatile, preprogrammed firmware that cannot be modified by the user. Additionally, custom presets and individual user settings are stored in memory to be adjusted by users at any time. During the development process,

regulations are recognized and applies to meet requirements, potential hazards are evaluated and mitigated for the safety of the patient and/or the operator. The Gemini 2 810 + 980 Soft Tissue Laser has software features that allows for access to training videos, user manuals and software updates.

5. 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
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- 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.
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- 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.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

	Gemini 2 810 + 980 Soft Tissue Laser Subject Device	**Gemini 810 + 980 Diode Laser Primary Predicate**	**Epic Pro Diode Laser System Reference predicate device**
Laser Classification	IV (4)	IV (4)	IV (4)

	Gemini 2 810 + 980 Soft Tissue Laser Subject Device	Gemini 810 + 980 Diode Laser Primary Predicate	Epic Pro Diode Laser System Reference predicate device
Type of Laser	Diode Laser	Diode Laser	Diode Laser
Laser Medium	GaAlAs	GaAlAs	InGaAsP
Product Code(s)	NVK; GEX; ILY	GEX; ILY	GEX
Wavelength	810 ± 10nm; or 980 ± 10nm; or 810nm and 980nm ± 10nm	810 ± 10nm; or 980 ± 10nm; or 810nm and 980nm ± 10nm	980nm ± 20nm
Average Output Power	Adjustable 0.1 - 2 Watts	Adjustable 0.1 - 2 Watts	Adjustable 0.1 – 25.0 Watts
Max Peak Output Power	150 Watts	20 Watts	150 Watts
Increments of Power Available	0.1 Watts	0.1 Watts	0.2-1 Watts
Operating Voltage	100-240 VAC	100-240 VAC	100V – 240V at 1.2A/0.5A
Current Frequency	50-60 HZ	50-60 HZ	50-60 HZ
Operation Mode	Pulsed	Pulsed	Pulsed, Continuous
Pulse Type	Gated	Gated	Gated
Battery	Lithium Ion Rechargeable	Lithium Ion Rechargeable	None
Delivery System	Quartz glass fiber & tip	Quartz glass fiber & tip	Fiber optic cable, handpiece and disposable fiber tips
Fiber/Tip Diameter	400 µm flexible fiber optic cable	400 µm flexible fiber optic cable	300 - 400 µm
Spot Size at Target	400 µm diameter; 25mm PBM Adapter, 7mm PBM Adapter and 3mm PBM Adapter	400 µm diameter; 25mm PBM Adapter	300 - 400 µm
Fiber Aiming Beam	2mW laser diode, 650nm, Class 1	5mW laser diode, 650nm, Class 1	5mW laser diode, 650nm
Activation Means	Wireless Foot Switch, with electronic access key	Wireless Foot Switch, with electronic access key	Wireless Foot Switch
Materials	Medical grade plastics, steel, stainless steel, aluminum, brass, glass, and electronic parts and	Medical grade plastics, steel, stainless steel, aluminum, brass, glass, and electronic parts and	Medical grade plastics, steel, stainless steel, aluminum, brass, and

	Gemini 2 810 + 980 Soft Tissue Laser Subject Device	Gemini 810 + 980 Diode Laser Primary Predicate	Epic Pro Diode Laser System Reference predicate device
	components	components	electronic parts and components
User Interface	Electroluminescent glass display with capacitive touch interface. Capacitive touch is a hard plastic.	Electroluminescent glass display with capacitive touch interface. Capacitive touch is sticker overlay.	Color front graphical user interface with dead front capacitive touch buttons.
Pre-Set Procedures	Three different categories – Surgical, Non-Surgical and Pain Relief	Four different categories - General Dentistry, Orthodontics, Hygiene and Pain Relief	Multiple pre-set procedures
Product Update Connectivity	Software update performed via app over Wi-Fi connection (wireless)	Software update performed via USB plugged into computer (hardwire)	Software update performed via USB plugged into computer (hardwire)
Haptic Feedback in Foot Pedal	Yes	n/a	n/a

The Gemini 2 810 + 980 Soft Tissue Laser has the equivalent indications for use and similar technological characteristics as that of the Predicate Device. The minor differences that exist between the Gemini 2 810 + 980 Soft Tissue Laser and the Predicate Device do not alter the fundamental scientific technology of the device, and most importantly have no effect on the ability of either laser system to output laser energy. Average power output is a dominant established factor when comparing laser devices and studies. These minor technological differences therefore raise no new questions of safety or effectiveness.

7. Performance Data:

The Gemini 2 810 + 980 Soft Tissue Laser was tested in accordance, and found to be in compliance, with the following national and international standards:

- 21 CFR 1040.10 & 1040.11 except for deviations pursuant to laser notice 50 dated June 24, 2007
- IEC 60601-2-22 Edition 4 2019
- IEC 60825-1Edition 3 2014
- AAMI/ANSI ES60601-1:2005/ (R) 2012 and A1:2012

- IEC 60601-1-2 Edition 4.0 2014-02
- AAMI/ANSI ST81:2004/(R)2016
- AAMI/ANSI ST79:2017
- AAMI/ANSI/ISO 17665-1:2006/(R)2013
- AAMI/ANSI/ISO 17665-2:2009-01-15
- AAMI/ANSI/ISO 10993-5:2009/(R)2014

Cleaning and Sterilization

Cleaning validation was conducted according to FDA Reprocessing Guidance. The cleaning procedure is validated for the reprocessing of the Anodized Aluminum Surgical Hand Piece with Fiber Connector.

Sterilization validation was conducted to validate a ten-minute gravity steam sterilization cycle at 135°C for the Anodized Aluminum Hand Piece Shell. Steam sterilization validation was conducted using a half-cycle method per ISO 17665-1 and -2 and demonstrated a SAL of 10^-6. The gravity cycle of 135°C at 10 minutes is validated for the Anodized Aluminum Hand Piece Shell.

Sterilization validation was conducted to validate a ten-minute gravity steam sterilization cycle at 135°C for the Intra oral PBM adapters. Steam sterilization validation was conducted using a half-cycle method per ISO 17665-1 and -2 and demonstrated a SAL of 10^-6. The gravity cycle of 135°C at 10 minutes is validated for the Intra oral PBM adapters.

Electrical Safety and EMC Testing

Testing to verify the conformity of the Gemini 2 810 + 980 Soft Tissue Laser, with the requirements of IEC 60601-1: (*Medical electrical equipment Part 1: General requirements for basic safety and essential performance*).

Testing to verify the conformity of the Gemini 2 810+980 Diode Laser with the requirements of IEC 60601-1-2: (*Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic compatibility*).

Testing to verify the conformity of the Gemini 2 810+980 Diode Laser to IEC 60825-1 (*Safety of laser products – Part 1: Equipment classification and requirements*).

Testing to verify the performance of Gemini 2 810+980 Diode Laser according to IEC 60601-2-22: (*Medical electrical equipment Part 2: Requirements for basic safety and essential performance of surgical, cosmetic, therapeutic, and diagnostic laser equipment*).

Software

Validation of the device's software in conformity with IEC 62304 (*Medical device software – Software lifecycle processes*) and software documentation of moderate level of concern per the FDA Guidance Document for Software Contained in Medical Devices

Non-Clinical
Bench testing was also conducted on the Gemini 2 810 + 980 Soft Tissue Laser and found that Gemini 2 810 + 980 Soft Tissue Laser meets the features and functions as identified in 21 CFR 1040.10.

Comparative bench testing was conducted on Azena's Gemini 2 810+980 Diode Laser against Biolase's Epic Pro for maximum peak power output and against Azena's Gemini 810+980 Diode Laser for average power output. It was found that the Gemini 2 810+980 Diode Laser is substantially equivalent to the original Gemini in terms of average power output of 2.0W. Testing against the Epic Pro concluded that the Gemini 2 performs equivalently, with a peak power of up to 150W.

Tissue temperature testing was conducted on all the Gemini 2 PBM adapters to show the mechanisms of action for ILY product code, lamp, infrared, therapeutic heating meet performance expectations.

The performance data, along with conformity to the recognized national and international standards cited above, demonstrates that the Gemini 2 810 + 980 Soft Tissue Laser performs as well as its predicate devices.

No clinical data was submitted for this Traditional 510(k).

8. Conclusions:

The Gemini 2 810 + 980 Soft Tissue Laser has the equivalent indications for use and characteristics as that of the Predicate Device. The minor technological differences that exist between the Gemini 2 810 + 980 Soft Tissue Laser and its predicate device do not alter the fundamental scientific technology of the device and raise no new questions of safety or effectiveness. Performance data demonstrates that the Gemini 2 810 + 980 Soft Tissue Laser is as safe and as effective as its Predicate Device. Comparative bench testing shows that the Gemini 2 810 + 980 Soft Tissue Laser is substantially equivalent to the Gemini 810 + 980 Soft Tissue Laser and Epic Pro.