



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

Re: K192617

Trade/Device Name: Gemini 810+980 Diode 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: GEX, ILY

Dated: January 2, 2020

Received: January 21, 2020

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 and Part 809); 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Mavadia-Shukla, Ph.D.  
Acting 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

510(k) Number (if known)

K192617

Device Name

Gemini 810 +980 Diode 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

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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.

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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)

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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**Section 5**  
**510(k) Summary**

**510(k) Summary of Safety and Effectiveness**

**Traditional 510(k) Premarket Notification**

**Submitter:**

Azena Medical, LLC  
3021 Citrus Cir Ste 180  
Walnut Creek, CA 94598

Phone: (800) 466 - 5273

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**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:** February 12, 2020

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

**Trade Name:** Gemini 810 + 980 Diode Laser

**Common Name(s):** Powered laser surgical instrument, Infrared lamp

**Classification Name(s):** Laser surgical instrument for use in general and plastic surgery and in dermatology; and infrared lamp

**Regulation Number:** **21 CFR 878.4810**

**Device Class:** Class II for all requested indications

**Product Code:** GEX, ILY

**Classification Panel:** General 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:** Elumi 810+980 Soft Tissue Laser  
**510(k):** K152032  
**Date Cleared:** September 16, 2015

**Reference Predicate Device:**

**Company:** Biolase Technology, Inc.  
**Device:** Epic 10  
**510(k):** K121286  
**Date Cleared:** September 28, 2012

**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):**

Gemini is an 810nm + 980nm soft tissue laser is intended for the incision, excision, ablation, vaporization, hemostasis and treatment of oral soft tissue and for pain relief using photobiomodulation. The Gemini laser operates at a wavelength of 810nm  $\pm$  10nm or at 980  $\pm$  10nm or a combination of both 810nm + 980nm wavelengths, with a maximum average power of 2 watts  $\pm$  20% and maximum peak pulse power of 20 watts  $\pm$  20% when in dual wavelength mode. The dual wavelength diode laser radiation is delivered through a flexible optical fiber and the Photobiomodulation (PBM) Adapter. Infrared laser energy is emitted from the fiber tips and the PBM Adapter when the wireless footswitch is depressed. The laser diodes are directly coupled to the flexible fiber optic cable that connects the laser unit to the surgical hand piece and to the disposable fiber tip and PBM Adapter that emits the energy to the target area. The laser diodes can simultaneously emit energy when Gemini is set to dual wavelength mode.

The Gemini unit comprises of six main assemblies: a Laser unit, a flexible fiber optic delivery system tethered to an anodized aluminum hand piece, disposable single-use fiber tips, PBM Adapter with spacers, a wireless footswitch, and an auxiliary power supply. The system also contains a 5mW 650nm laser diode coupled to the same fiber optic cable to produce the red aiming light. The laser system is contained within a compact lightweight impact resistant molded plastic housing that contains a laser diode assembly, a laser power controller PCB, an Electroluminescent Display connected to an interface PCB, a touch sensitive selection panel with status lights, and a rechargeable Lithium Battery. The hand piece used by the practitioner consists of an anodized aluminum cylindrical body which encloses the optics used to transfer

the laser energy to the single-use fiber tips and the PBM Adapter. The LED illumination system for lighting the work area will be off for PBM Adapter.

The laser's visible light is designed to aid the clinician in aiming the tip of the delivery fiber into the target tissue. Additionally, a bright white light from the LEDs in the hand piece illuminates target work area during procedures through the translucent disposable laser tips.

The PBM Adapter is an accessory attachment to the Gemini laser system to increase the spot size of the laser beam, allowing the Gemini Laser to provide near-infrared laser energy to a tissue surface for the purpose of photobiomodulation. Affected muscles and/or joints must be exposed to an adequate level of laser energy over a period of time to provide effective results. The spot size of the PBM Adapter is 25 mm. The PBM Adapter operates at 810nm  $\pm$  10nm wavelength with a maximum average power of 1 watt  $\pm$  20%.

A PBM spacer is attached to the PBM Adapter. The spacer is a single-use disposable piece designed to ensure proper working distance to target tissues and limit the risk of cross contamination between patients. The PBM Adapter is designed to only work with the Gemini Laser System.

Gemini 810 + 980 Diode Laser utilizes non-volatile, preprogrammed firmware that cannot be modified by the user. During the development process, requirements are met, hazards are evaluated and mitigated for the safety of the patient and /or the operator and the firmware. It does not capture any data related to patients. The Gemini software focuses on the functional and technical design for the Gemini laser. This includes the graphical user interface (GUI), the control of the laser drivers, sound, tip illumination and aiming light.

## **5. INDICATIONS FOR USE:**

*The indications for use are identical to those of the previously cleared Predicate Device, ELUMI 810+980 Soft Tissue Laser and similar to the Epic 10 Laser. The only difference with the ELUMI 810+980 Soft Tissue Laser is that device is not cleared for the indication of Pain Management.*

### 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

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- 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.

#### 6. **COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:**

	<b>Gemini 810 + 980 Diode Laser</b>	<b>Elumi Soft Tissue Laser Primary Predicate</b>	<b>Epic 10 Reference predicate device</b>
<b>Laser Classification</b>	IV (4)	IV (4)	IV (4)
<b>Type of Laser</b>	Diode Laser	Diode Laser	Diode Laser
<b>Laser Medium</b>	GaAIAs	GaAIAs	InGaAsP
<b>Product Code(s)</b>	GEX; ILY	GEX	GEX; ILY
<b>Wavelength</b>	810 ± 10nm; or 980 ± 10nm; or 810nm and 980nm ± 10nm	810 ± 10nm; or 980 ± 10nm; or 810nm and 980nm ± 10nm	940 ± 10 nm
<b>Average Output Power</b>	Adjustable 0.1 - 2 Watts	Adjustable 0.1 - 2 Watts	Adjustable 0.1 – 10.0 Watts
<b>Max Peak Output Power</b>	20 Watts	20 Watts	10 watts
<b>Increments of Power Available</b>	0.1 Watts	0.1 Watts	0.1 Watts
<b>Operating Voltage</b>	100-240 VAC	100-240 VAC	100-240 VAC
<b>Current Frequency</b>	50-60 HZ	50-60 HZ	50-60 Hz
<b>Operation Mode</b>	Pulsed	Pulsed	Pulsed, Continuous
<b>Pulse Type</b>	Gated	Gated	Gated
<b>Battery</b>	Lithium Ion Rechargeable	Lithium Ion Rechargeable	Lithium Ion Rechargeable
<b>Delivery System</b>	Quartz glass fiber & tip	Quartz glass fiber & tip	Quartz glass fiber & tip

<b>Fiber/Tip Diameter</b>	400 µm flexible fiber optic cable	400 µm flexible fiber optic cable	200 µm, 300 µm, 400 µm flexible fiber Optic Cable
<b>Spot Size at Target</b>	400 µm diameter; 25mm PBM Adapter	400 µm diameter	200 µm, 300 µm, 400 µm diameter; adjustable 15-30 mm Pain management handpiece
<b>Fiber Aiming Beam</b>	5mW laser diode, 650nm, Class 1	5mW laser diode, 650nm, Class 1	Laser Diode max. 1mW, 635 ± 10 nm, class 1
<b>Activation Means</b>	Wireless Foot Switch, with electronic access key	Wireless Foot Switch, with electronic access key	Wireless Foot Switch, with electronic access key

The Gemini 810 + 980 Diode Laser has the equivalent indications for use and technological characteristics as that of the Predicate Device with the exception of pain management, which is indicated in the reference predicate device indications for use. The difference that exist between the Gemini 810 + 980 Diode Laser and the Predicate Devices 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 at safe and effective levels of average power.

## 7. **Performance Data:**

The Gemini 810 + 980 Diode 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 3.1 2012-10
- IEC 60825-1Edition 2.0 2007-03
- 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 recovery method for the Anodized Aluminum Surgical Hand Piece with Fiber Connector achieved 78.5% and 77.6% recoveries for protein and hemoglobin respectively. All cleaned devices for the Anodized Aluminum Surgical Hand Piece with Fiber Connector were found to contain < 5.4 µg/cm<sup>2</sup> and < 1.6 µg/cm<sup>2</sup> for protein and hemoglobin respectively. 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 fifteen -minute gravity steam sterilization cycle at 135°C for the Anodized Aluminum Hand Piece Shell. There was no growth of the biological indicators that had been exposed to steam with the test article. The verified half cycle indicates that a full gravity cycle of not less than 15 minutes at 135°C is capable of a 12 log reduction and will provide a 10<sup>-6</sup> sterility assurance level of a worst case population. The gravity cycle of 135°C at 15 minutes is validated for the Anodized Aluminum Hand Piece Shell.

### **Electrical Safety and EMC Testing**

Testing to verify the conformity of the Gemini 810+980 Diode 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 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 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 810+980 Diode Laser according to IEC 60601-2-22: (*Medical electrical equipment Part 2: Particular 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*).

### **Non-Clinical**

Bench testing was also conducted on the Gemini 810+980 Diode Laser and found that Gemini meets the features and functions as identified in 21 CFR 1040.10.

Comparative bench testing was conducted on Gemini 810+980 Diode Laser using the new PBM Adapter in comparison with Biolase Epic 10 with pain therapy handpiece to ensure equivalence in pain management laser energy output, therefore ensuring new indication for use equivalence. The testing resulted in similar power density and spot size. It was found that the Gemini with PBM Adapter is substantially equivalent to Epic 10 with pain therapy handpiece and laser energy output.

Skin temperature testing was also conducted. The mechanisms of action for ILY product code, lamp, infrared, therapeutic heating, is to raise the skin temperature to 40-45 degrees Celsius and maintain for a minimum of 10 minutes. It was determined that the Gemini 810+980 Diode

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Laser with PBM Adapter increases topical heat at the tissues level to 40 degrees Celsius and can maintain this temperature for a minimum of 10 minutes during treatment.

This performance data, along with conformity to the recognized national and international standards cited above, demonstrates that the Gemini 810 + 980 Diode Laser supports and performs as well as or better than its predicate devices.

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

## **8. Conclusions:**

The Gemini 810 + 980 Diode Laser has the equivalent indications for use and technological characteristics as that of the Predicate Device with the exception of the pain management indication. The minor differences in indications do not raise any new questions of safety or effectiveness. The original indications in Gemini were already cleared through a prior 510(k) (K152032). The minor technological differences that exist between the Gemini 810 + 980 Diode 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 810 + 980 Diode Laser is as safe and as effective as its Predicate Device. The addition of the pain management indication is equivalent to the reference device Biolase's Epic 10. Comparative bench testing shows that the Gemini laser is substantially equivalent when it comes to the pain management function against the Epic 10