



Food and Drug Administration
10903 New Hampshire Avenue
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September 16, 2015

Azena Medical, LLC
% Mr. Dave Yungvirt
Third Party Review Group, LLC
45 Rockefeller Plaza Suite 2000
New York, New York 10111

Re: K152032

Trade/Device Name: ELUMI 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: GEX

Dated: August 27, 2015

Received: September 1, 2015

Dear Mr. 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 (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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152032

Device Name

ELUMI 810 + 980 Soft Tissue Laser

Indications for Use (Describe)

The indications for use are identical to those of the previously cleared Predicate Device. The ELUMI 810+980 Soft Tissue Laser is intended for the incision, excision, ablation, vaporization, hemostasis, and treatment of oral soft tissue.

The following are the oropharyngeal indications for use:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Gingivoplasty
- Hemostasis and coagulation
- Incision and drainage of abscess
- Operculectomy
- Pulpotomy
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Vestibuloplasty
- Laser Soft Tissue Curettage
- Tissue retraction
- Frenectomy and Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingival incision and excision
- Implant recovery
- Leukoplakia
- Oral papillectomies
- Pulpotomy as an adjunct to root canal therapy
- Reduction of bacterial level (decontamination) and inflammation
- Treatment of aphthous ulcers
- Lesion (tumor) removal
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Removal of Diseased, Infected, Inflamed and necrotic 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 necrotic, diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
- Light activation for bleaching materials for teeth whitening
- 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.

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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
21 Massolo Dr, 2nd Floor – Unit C
Pleasant Hill, CA 94523

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
21 Massolo Drive
FI2 Unit C
Pleasant Hill, CA 94523

Contact Person: Alexandre B. Di Sessa
Founder & CEO
Phone: 800-466-5273
Email: 510k@azenamedical.com

Date of Preparation: April 6, 2015

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

Trade Name: *ELUMI 810 + 980 Soft Tissue Laser*

Common Name(s): Diode laser, powered laser surgical instrument

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

Regulation Number: **§878.4810**

Device Class: Class II for all requested indications

Product Code: GEX

Classification Panel: General and Plastic Surgery & Others

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

Predicate Device:

Company: QuickLase Limited
Device: QuickLase DUAL+
510(k): K100474
Date Cleared: March 16, 2010

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 ELUMI 810 + 980 Soft Tissue Laser, or ELUMI, is a battery-powered counter top surgical and therapeutic device designed for a wide variety of oral soft tissue procedures and dental teeth whitening.

The ELUMI comprises of five main assemblies; of a Laser Unit, a flexible fiber delivery system tethered to an anodized aluminum hand piece, disposable single-use fiber tips, a wireless footswitch, and an auxiliary power supply. Infrared laser energy is emitted from the fiber tips when the wireless footswitch is depressed. The ELUMI Laser Unit contains two single-emitter solid-state laser diodes of 10.0-watt peak output power each (Class IV laser), one lasing at 810nm and the other at 980nm wavelength. The laser diodes can simultaneously emit laser energy when ELUMI is set to Dual Wavelength mode. The laser diodes are directly coupled to the flexible fiber optic cable that connects the Laser Unit to the surgical hand piece and disposable fiber tip that emits the energy to the target area. The system also contains a 5mW power, 650nm laser diode coupled to the same fiber optic cable to produce the red aiming light. The laser's visible light is designed to aid the clinician in aiming the tip of the delivery fiber onto the target tissue. Additionally, a bright white light from two LEDs in the hand piece illuminates target tissue during procedures through the translucent disposable laser tips. The auxiliary power supply connects to the Laser Unit and is used to charge the system battery and as a power source for the system in the event of low battery capacity.

5. *Statement of intended use:*

The indications for use are identical to those of the previously cleared Predicate Device.

The ELUMI 810+980 Soft Tissue Laser is intended for the incision, excision, ablation,

vaporization, hemostasis, and treatment of oral soft tissue.

The following are the oropharyngeal indications for use:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Gingivoplasty
- Hemostasis and coagulation
- Incision and drainage of abscess
- Operculectomy
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- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Vestibuloplasty
- Laser Soft Tissue Curettage
- Tissue retraction
- Frenectomy and Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingival incision and excision
- Implant recovery
- Leukoplakia
- Oral papillectomies
- Pulpotomy as an adjunct to root canal therapy
- Reduction of bacterial level (decontamination) and inflammation
- Treatment of aphthous ulcers
- Lesion (tumor) removal
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Removal of Diseased, Infected, Inflamed and necrotic 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 necrotic, diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
- Light activation for bleaching materials for teeth whitening
- Laser-assisted whitening/bleaching of teeth

6. *Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device:*

The proposed ELUMI 810 + 980 Soft Tissue Laser has the following technological similarities

to the Predicate Device:

- the same laser type: solid state diode,
- the same laser medium: GaAlAs,
- the same working beam wavelengths: 810nm or 980nm, dual wavelength (810nm + 980nm),
- the same average power output up to 2.0 Watts,
- the same increments of average power available: 0.1 Watts,
- the same maximum peak output power: 10 Watts @ 810nm, 10 Watts @ 980nm, 20 Watts @ Dual Wavelength,
- the same pulse type: gated,
- the same delivery system and fiber diameter: 400 µm quartz glass fiber,
- the same cutting method: tissue contact,
- the same patient contacting components: quartz glass fiber,
- the equivalent user interface, and
- the same activation means: foot switch.

7. *Statement of how the functional characteristics of the device compare to those of the predicate or legally marketed device:*

The proposed ELUMI 810 + 980 Soft Tissue Laser has the following functional similarities to the Predicate Device:

- the same indications for use,
- the same operating principle,
- the same basic construction,
- the same shelf life, and
- the same packaging materials and processes.

8. *Performance Data:*

The ELUMI 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
- IEC 60825-1
- AAMI/ANSI ES60601-1
- IEC 60601-1-2
- AAMI/ANSI ST81:2004/(R)2010
- AAMI/ANSI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013
- AAMI/ANSI/ISO 17665-1:2006
- AAMI/ANSI/ISO 17665-2:2009
- AAMI/ANSI/ISO 10993-5:2009

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 $\mu\text{g}/\text{cm}^2$ and < 1.6 $\mu\text{g}/\text{cm}^2$ 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 10⁻⁶ 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.

Bench testing was performed to measure the ELUMI 810 + 980 Soft Tissue Laser's average output power side-by-side with the Predicate Device. The intended performance of these devices, based on IEC 60601-2-22, requires that the laser average power output only vary from the device's settings by less than $\pm 20\%$ of the setting. The results of the bench testing demonstrate that both the ELUMI 810 + 980 Soft Tissue Laser and the Predicate Device satisfy this IEC 60601-2-22 requirement.

Bench testing was also conducted to compare features and functions of the ELUMI 810+980 Soft Tissue Laser to the Predicate Device, and found that ELUMI is substantially equivalent to the Predicate Device by having identical features and functions as identified in 21 CFR 1040.10.

Additionally, an animal study was conducted to evaluate the histological effects on pig liver soft tissue of the Elumi 810+980 Soft Tissue Laser system, and compare the results to those of the Predicate Device. The results of this new animal study demonstrate that the Elumi 810+980

Traditional 510(k)

Soft Tissue Laser and the Predicate Device have similar effects on soft tissue, despite slight differences in average output power and operation modes.

This performance data, along with conformity to the recognized national and international standards cited above, demonstrates that the ELUMI 810 + 980 Soft Tissue Laser is as safe and as effective as its Predicate Device.

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

9. Technological Characteristics:

The ELUMI 810 + 980 Soft Tissue Laser has the same fundamental technological characteristics as the Predicate Device.

	ELUMI 810 + 980 Soft Tissue Laser	QuickLase DUAL+
Laser Classification	IV (4)	IV (4)
Type of Laser	Diode Laser	Diode Laser
Laser Medium	GaAIs	GaAIs
Wavelength	810 ± 10nm; or 980 ± 10nm; or 810nm and 980nm ± 10nm	810 ± 10nm; or 980 ± 10nm; or 810nm and 980nm ± 10nm
Average Output Power	Adjustable 0.1 - 2 Watts	Adjustable 0.1 - 10 Watts
Max Peak Output Power	10 Watts @ 810nm; 10 Watts @ 980nm; 20 Watts @ 810nm + 980nm	10 Watts @ 810nm; 10 Watts @ 980nm; 20 Watts @ 810nm + 980nm
Increments of Power Available	0.1 Watts	0.1 Watts
Operating Voltage	100-240 VAC	100-240 VAC
Current Frequency	50-60 HZ	50-60 HZ
Operation Mode	Pulsed	Continuous, Pulsed
Pulse Type	Gated	Gated
Battery	Lithium Ion Rechargeable	Lithium Ion Rechargeable
Delivery System	Quartz glass fiber & tip*	Quartz glass fiber
Fiber/Tip Diameter	400 µm core	400 µm core
Fiber Aiming Beam	5mW laser diode, 650nm, Class 1	5mW laser diode, 645nm, Class 1
Activation Means	Wireless Foot Switch, with electronic access key	Wired Foot Switch, with electronic access key

[Traditional 510\(k\)](#)

*The quartz glass fiber within ELUMI's single-use fiber tip is the only system component that comes in direct or indirect contact with patients. This fiber is exactly the same fiber, sourced from the same supplier, and used in the same manner as the fiber used with another FDA cleared dental soft tissue laser, the SL3 (K102639).

10. Conclusions:

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