Rohrer Aesthetics, LLC
Mark Rohrer
President
105 Citation Court
Homewood, Alabama 35209

July 9, 2019

Re: K191162
Trade/Device Name: EpiLaze Multi-wavelength 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: April 24, 2019
Received: May 1, 2019

Dear Mark Rohrer:

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,

Neil R.P. Ogden
Assistant Director, THT4A4
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: 0MB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

51O(k) Number *(if known)*
K191162

Device Name
EpiLaze Multi-wavelength Laser

Indications for Use *(Describe)*

Intended Use:
The EpiLaze Multi-wavelength Laser is intended for use in dermatologic and general surgical procedures.

Indication for Use for the 1064nm wavelength:

- The Standard Hair Removal (STANDARD) and Smooth Flow Technology Hair Removal (SFT) Modes are intended for
  - permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen; and
  - treatment of Pseudo folliculitis Barbae (PFB).

Indication for Use for the 810nm wavelength:

- The Standard Hair Removal (STANDARD) and Smooth Flow Technology Hair Removal (SFT) Modes are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen.

Indication for use for the 755nm wavelength:

- The Standard Hair Removal (STANDARD) and Smooth Flow Technology Hair Removal (SFT) Modes are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen.

The STANDARD mode can be used on all skin types (Fitzpatrick I-VI), including tanned skin. The SFT mode can only be used on Fitzpatrick skin type I-IV. Do not use the SFT mode on tanned skin.

Type of Use *(Select one or both, as applicable)*

X 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
EpiLaze Multi-wavelength Laser

This 510(K) Summary of safety and effectiveness for the EpiLaze Multi-wavelength Laser is submitted in accordance with the requirements of 21 CFR 807.92.

Applicant:	Rohrer Aesthetics, LLC
Address:	Rohrer Aesthetics, LLC 105 Citation Court Homewood, AL 35209
Contact Person:	Mr. Mark Rohrer
Telephone:	205-356-1172 – phone mrohrer@rohreraesthetics.com
Preparation Date:	July 5, 2019
Device Trade Name:	EpiLaze Multi-wavelength Laser
Common Name:	Surgical Powered Lasers and Delivery Devices/Hand piece Accessories
Regulation Name:	Laser surgical instrument for use in general and plastic surgery and dermatology
Regulation Number:	21 CFR 878.4810 (Product Code: GEX)
Primary Predicate Device:	Modified Alma Lasers Soprano XL Family of Multi-application & Multi-technology Platform, Soprano Yag Hand Piece (Soprano Ice, K170626)
Reference Predicate Device:	Multilaser System (K123777)
Regulatory Class:	Class II Prescription Use
Description of the EpiLaze Multi-wavelength Laser:	The EpiLaze Multi-wavelength Laser is a microprocessor-controlled, user friendly 755nm, 810nm and 1064nm Diode laser system using a sealed diode pack that produces a maximum energy of 120J/cm^2. The system incorporates a diode pack within each hand piece, and the energy is delivered from the hand piece directly to the desired target. The EpiLaze Multi-wavelength Laser consists of a console, a touch screen user interface, a footswitch and 2 handpieces
Intended use of the EpiLaze Multi-wavelength Laser:	Intended Use: The EpiLaze Multi-wavelength Laser is intended for use in dermatologic and general surgical procedures. Indication for Use for the 1064nm wavelength: • The Standard Hair Removal (STANDARD) and Smooth

Flow Technology Hair Removal (SFT) Modes are intended for

- permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen, and
- treatment of Pseudo folliculitis Barbae (PFB).

Indication for Use for the 810nm wavelength:
• The Standard Hair Removal (STANDARD) and Smooth Flow Technology Hair Removal (SFT) Modes are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen.

Indication for use for the 755nm wavelength:
• The Standard Hair Removal (STANDARD) and Smooth Flow Technology Hair Removal (SFT) Modes are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen.

The STANDARD mode can be used on all skin types (Fitzpatrick I-VI), including tanned skin. The SFT mode can only be used on Fitzpatrick skin type I-IV. Do not use the SFT mode on tanned skin.

Performance Data:

The following performance data was provided in support of the substantial equivalence determination:

ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012 Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance;

IEC 60601-1-2:2014 Test for Medical Equipment for General Requirements for basic safety and essential performance: electromagnetic compatibility;

IEC 60601-2-22 Medical Electrical Equipment-Part 2-22: Requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser Equipment;

Bench testing to show that the difference between the set and delivered energy parameters of the device falls within specifications.

Software verification and validation testing was performed per FDA’s guidance, General Principles of Software Validation; Final Guidance for Industry and FDA Staff, dated January 11, 2002.

Biocompatibility testing was not needed as the relevant parts

are identical in the subject device and reference predicate.

Results of Clinical Study: A human clinical study was not required as the device is identical to the predicate device.

Technical Specifications Comparison:

1064nm

Characteristic	EpiLaze (510K Pending)		Soprano Ice (K170626)	
Wavelength (nm)	1064		1064	
Laser Media	Solid State		Solid State	
Mode	STANDARD	SFT	HR	SHR
Spot Size	10mm x 10mm with optional tapered tip 6mm		10mm x 10mm with optional tapered tip 6mm	
Pulse width (msec)	3.3-280		3.3-280	
Pulse Repetition rate (Hz)	0.5-3	5-10	0.5-3	5-10
Energy Density (Fluence, J/cm^2)	2-120	2-20	2-120	2-20
Delivery Devices	Nonsterile, Reusable, cleanable		Nonsterile, Reusable, cleanable	

Characteristic	EpiLaze (510K Pending)			Soprano Ice (K170626/140009)		
Wavelength (nm)	810, 755			810, 755		
Laser Media	Solid State			Solid State		
Mode	STANDARD	SFT		HR	SHR	LB
Spot Size	810nm 12mm x 10mm 20mm x 10mm Optional tapered tips: 6mm and 12mm 755nm 15mm x 10mm			810nm 12mm x 10mm 20mm x 10mm Optional tapered tips: 6mm and 12mm 755nm 15mm x 10mm		
Pulse width (msec)	3.3-200			3.3-200		
Pulse Repetition rate (Hz)	0.5-3	5-10		0.5-3	5-10	2
Energy Density (Fluence, J/cm^2)	2 - 120	2-20		2-120	2-20	755nm Up to 25, 810nm Up 40
Delivery Devices	Nonsterile, Reusable, cleanable			Nonsterile, Reusable, cleanable		

Technical Specifications Comparison:

The technical specifications of the subject and predicate devices for 1064 nm wavelength are identical.

The technical specifications of the subject and predicate devices for 810 and 755 nm wavelengths are identical for comparable modes. The subject device does not have LB mode and related indications for use, as in the predicate.

Indication for Use Comparison:

	EpiLaze (510K Pending)	Soprano Ice (K170626)	Comparison
1064nm Laser	The Standard Hair Removal (STANDARD) and Smooth Flow Technology Hair Removal (SFT) Modes are intended for - Permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-	The Hair Removal (HR) and Super Hair Removal (SHR) Mode are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen.	Identical

	EpiLaze (510K Pending)	Soprano Ice (K170626)	Comparison
	growing when measured at 6,9 and 12 months after the completion of a treatment regimen, and - Treatment of Pseudo folliculitis Barbae (PFB). The STANDARD mode can be used on all skin types (Fitzpatrick I-VI), including tanned skin. The SFT mode can only be used on Fitzpatrick skin type I-IV. Do not use the SFT mode on tanned skin.	Treatment of Pseudo folliculitis Barbae (PFB) Use on all skin types (Fitzpatrick I-VI), including tanned skin.	
810nm Laser	The Standard Hair Removal (STANDARD) and Smooth Flow Technology Hair Removal (SFT) Modes are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen. The STANDARD mode can be used on all skin types (Fitzpatrick I-VI), including tanned skin. The SFT mode can only be used on Fitzpatrick skin type I-IV. Do not use the SFT mode on tanned skin.	The Hair Removal (HR) and Super Hair Removal (SHR) Mode are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen. The treatment of benign vascular and pigmented lesions in LB mode. Use on all skin types (Fitzpatrick I-VI), including tanned skin	Different The Epilaze cannot treat benign vascular lesions or pigmented lesions since it does not have LB mode, as in the predicate.

	EpiLaze (510K Pending)	Soprano Ice (K170626)	Comparison
755nm Laser	The Standard Hair Removal (STANDARD) and Smooth Flow Technology Hair Removal (SFT) Modes are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen. The STANDARD mode can be used on all skin types (Fitzpatrick I-VI), including tanned skin. The SFT mode can only be used on Fitzpatrick skin type I-IV. Do not use the SFT mode on tanned skin.	The Hair Removal (HR) and Super Hair Removal (SHR) Mode are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen. The treatment of benign vascular and pigmented lesions in LB mode. Use on all skin types (Fitzpatrick I-VI), including tanned skin	Different The Epilaze cannot treat benign vascular lesions or pigmented lesions since it does not have LB mode, as in the predicate.

Conclusion: The subject device EpiLaze Multi-wavelength Laser is substantially equivalent to the primary predicate device Modified Alma Lasers Soprano XL Family of Multi-application & Multi-technology Platform, Soprano Yag Hand Piece (Soprano Ice, K170626) for comparable indications for use.