March 17, 2020

A.R.C. Laser GmbH
Angela Thyzel
General Manager
Bessemer St. 14
Nurnberg, 90411 De

Re: K192272
Trade/Device Name: Wolf 445nm
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: February 3, 2020
Received: February 10, 2020

Dear Angela Thyzel:

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) 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

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)*
K192272

Device Name
Wolf 445nm

Indications for Use *(Describe)*

The Wolf 445nm is intended for incision, excision, vaporization, ablation, hemostasis and coagulation of soft tissue.

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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510(k) Summary – K192272

Submitter: A.R.C. Laser GmbH
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90411, Nurnberg
Germany

Contact person : Angela Thyzel, General Manager
Phone : 0911-21779-0
Fax : 0911-21779-99
E-Mail: a.thyzel@arclaser.de

Date Prepared: March 6, 2020

Device Trade Name: Wolf 445nm

Common Name: Diode Laser System

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

Device product code: GEX

Device Classification 21 CFR 878.4810

Predicate Devices: Aura Laser System, K951034, Primary Predicate
SiroLaser Blue, K180044, Reference Predicate

Device Description:
The Wolf Diode Lasers are a family of products with a laser diode as the beam source. Dependent on the chosen diode the laser system can radiate one wavelength with either 445nm, 980nm or 1470nm. This submission refers to and includes only one model, the Wolf 445nm.
The Wolf 445nm is a compact diode laser with a high resolution color touchscreen for user control. The laser utilizes a green (532nm) aiming beam diode to indicate the area to be irradiated by the laser beam.

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510(k) Summary – K192272

Indications for Use: The Wolf 445nm is intended for incision, excision, vaporization, ablation, hemostasis and coagulation of soft tissue.

Comparison of Technological Characteristics with the Predicate Devices

The primary predicate device is the Aura laser system (K951034), a KTP laser with a wavelength of 532nm with same intended use as the subject device.
The SiroLaser Blue, K180044, is a reference device, with the same intended use although is used for dental applications, shares the same wavelength, the same product code GEX, same device class and same classification name and number.

Specification	**Subject Device Wolf 445nm**	**Primary Predicate Device Aura Laser System**	**Reference Predicate Device SIROLaserBlue**
510(k) #	K192272	K951034	K180044
Regulation #	878.4810	878.4810	878.4810
Class Code	GEX	GEX	GEX & ILY
Class	II	II	II
Indications for Use	The Wolf 445nm is intended for use in incision/excision, vaporization, ablation, hemostasis and coagulation of soft tissue	Aura XP is intended for use in in incision/excision, vaporization, ablation, hemostasis and coagulation of soft tissue	SIROLaserBlue is intended for intra and extra oral surgery including incision, excision, hemostasis, coagulation & vaporization of soft tissue
Use of device	RX only	RX only	RX only
Laser type	Diode Laser	Flash Lamp Pulsed KTP Laser	Diode Laser
Laser power	0.5 W to 10 W	0.5 W to 15 W	0.2 W – 3.0 W
Wavelength	445 nm	532 nm	445 nm, 660 nm, 970 nm
Laser Class	4	4	4
Operation mode	Pulsed, Continuous Wave (CW) or Single Pulse (SP)	Pulsed, Quasi continuous wave	Continuous wave (CW) or Pulsed
Pulse length/ duration	≤ 4 Watt: 1 ms to 45 sec and CW > 4 Watt: 1 ms to 60 ms	1 to 50 milliseconds in 1 ms increments, then .1 to 1 sec in 0.1 increment, then .5 sec increments to continuous	10 µs to 0.99 sec.
Pulse frequency	≤ 4 Watt: 0.01 Hz to 500 Hz and SP > 4 Watt: 0.02 Hz to 6.6 Hz and SP	0.5 Hz to 5 Hz	1 Hz to 10 kHz
Aiming beam wavelength	532 nm	635 nm	660 ± 5 nm
Aiming beam power	≤ 5 mW	5 mW	max. 1 mW

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510(k) Summary – K192272

Comparison of Technological Characteristics with the Predicate Devices (continuation)

Specification	Subject Device Wolf 445nm	Primary Predicate Device Aura Laser System	Reference Predicate Device SIROLaserBlue
Use in combination	Delivery devices optical fibers 300 µm, 400 µm and 600 µm with or without hand pieces	Delivery devices - Multiple Aura Fibers and accessories for various applications	Delivery devices, fibers 200 µm, 320 µm
Cooling	Air	Air	Air
Display	Touch screen	Buttons and regulators	Touch screen
Main power Supply	100-240 V~, 47-63 Hz, 1.06-0.45 A	120 V AC/ 15 AMPS 230 V AC/ 10 AMPS	15 V DC 6.66 A max. 100 VA MPU101-106
Dimensions of system	H 10.06 cm (3.9 inches) W 20.3 cm (7.9 inches) L 23.9 cm (9.4 inches)	H 41 cm (16 inches) W 30.5 cm (12 inches) L 58 cm (23 inches)	H 18.2 cm (7.1 inches) W 19.7 cm (7.7 inches) L 18.9 cm (7.4 inches)
Weight	2.8 kg (6.17 pounds)	27 kg (60 pounds)	1.3 kg (2.86 pounds)

Performance Data

The safety and effectiveness determination of the 445nm subject device compared to the primary predicate with wavelength 532nm is supported by the Electrical Safety, EMC, Software, and non-clinical comparison bench tests provided in the submission.

Non clinical testing :

A comparison bench test between 445 nm and 532 nm laser devices was conducted with the purpose of demonstrating that the Wolf 445 nm provides as safe & effective performance data as a KTP Laser (532 nm) in terms of tissue interaction processes.
The cut depth (effectiveness) and thermal damage (safety) zones of the 445nm laser device were used for the purpose of comparison.

Following the tests, histological samples were evaluated for areas of visible alteration of depth and width of the incision as well as zones of thermal and mechanical damage created by the tests.

Electrical Safety and EMC testing:

Electrical safety and EMC testing were conducted on the Wolf 445nm, consisting of Diode laser console and optical fibers.
The Wolf 445nm system has been tested for Electrical Safety according to IEC 60601-1:2005 A1:2012 and /or EN 60601-1:2006/A1:2013, for Laser Safety according to IEC 60825-1: 2014 (edition 3.0), for Safety of laser according to IEC 60825-1:2014 and IEC 60601-2-22:2007/A1:2012, for Usability with IEC 60601-1-6:2010/A1:2013 and IEC 62366:20017, AMD1:2014.
Electromagnetic Compatibility was tested according to IEC 60601-1-2:2014, (edition 4.0).

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

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The software is considered as a moderate level of concern and the documentation was provided accordingly.

Summary
Based on the clinical performance, technological characteristics and performance data as documented in this submission, the Wolf 445nm was found to have a safety and effectiveness profile that is similar to the predicate devices.

Conclusion
The safety and effectiveness determination between the subject and the predicate devices is supported by the performance data provided in the submission, the electrical and EMC testing, the software verification and validation testing and the non-clinical bench test demonstrating that the Wolf 445nm performs comparably to the predicate device that is currently marketed for the same intended use.

Animal or clinical studies: None