September 1, 2022

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

Re: K220531
Trade/Device Name: Fox 810 and FOX 980
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: July 15, 2022
Received: July 21, 2022

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); 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,

Jianting Wang
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K220531

Device Name
FOX 810 and FOX 980

Indications for Use *(Describe)*

FOX 810:
Indicated for surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissues in medical specialties including dermatology, dentistry, gastroenterology, general surgery, neurosurgery, otolaryngology, and pulmonology.

FOX 980:
Indicated for surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissues in medical specialties including dermatology, dentistry, gastroenterology, general surgery, genitourinary, gynecology, neurosurgery, otolaryngology, orthopedics, pulmonology, and thoracic surgery.

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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**K220531 - 510(k) Summary**

| | |
|---|---|
| Submitter: | A.R.C. Laser GmbH<br>Bessemer St. 14 90411,<br>Nuremberg<br>Germany |
| Contact person: | Angela Thyzel, General Manager |
| Phone: | 0911-21779-0 |
| Fax: | 0911-21779-99 |
| E-Mail: | a.thyzel@arclaser.de |
| Type of 510(k): | Traditional |
| Date Prepared: | August 8th, 2022 |
| Device Trade Name: | FOX 810 and FOX 980 |
| 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: | Primary Predicates: Fox Q-980, Fox Q-1064, Fox Q-810 (K073322) |
| | Secondary Predicates: Fotona XPulse Pro Laser Platform (K202991) |

**Device Description:**

The FOX 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 factory set wavelength with either 810nm or 980nm. The FOX is a compact diode laser with a high-resolution color touchscreen for user control.

**Indications for Use**:

FOX 810:

Indicated for surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissues in medical specialties including dermatology, dentistry, gastroenterology, general surgery, neurosurgery, otolaryngology, and pulmonology.

FOX 980:

Indicated for surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissues in medical specialties including dermatology, dentistry, gastroenterology, general surgery, genitourinary, gynecology, neurosurgery, otolaryngology, orthopedics, pulmonology, and thoracic surgery.

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**Comparison between subject and primary predicate devices Fox Q-810, Fox Q-980, Fox Q-1064 and secondary predicate device Fotona XPulse Pro Laser Platform**

| **Specification** | **Subject device**<br>**FOX- including FOX 810 and FOX 980** | **Primary Predicate Device**<br>**Fox Q-810, Fox Q-980, Fox Q-1064** | **Predicate Device**<br>**XPulse Pro Laser Platform** |
|---|---|---|---|
| **510(k) number** | K220531 | K073322 | K202991 |
| **Manufacturer** | A.R.C Laser GmbH | A.R.C Laser GmbH | Fotona |
| **Regulation-Number** | 21 CFR 878.4810 | 21 CFR 878.4810 | 21 CFR 878.4810 |
| **Product Code** | GEX | GEX | GEX |
| **Regulatory Class** | Class II | Class II | Class II |
| **Indications for Use** | FOX 810:<br>Indicated for surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissues in medical specialties including dermatology, dentistry, gastroenterology, general surgery, otolaryngology, and pulmonology.<br>FOX 980:<br>Indicated for surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissues in medical specialties including dermatology, dentistry, gastroenterology, general surgery, genitourinary, gynecology, otolaryngology, orthopedics, pulmonology, and thoracic surgery. | Fox Q-810:<br>Indicated for surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissues in medical specialties including dermatology, dentistry, gastroenterology, general surgery, neurosurgery, otolaryngology, ophthalmology, and pulmonology.<br>Fox Q-980:<br>Indicated for surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissues in medical specialties including dermatology, dentistry, gastroenterology, general surgery, genitourinary, gynecology, neurosurgery, otolaryngology, orthopedics, ophthalmology, pulmonology, and thoracic surgery. | From IFU of XPulse Pro Laser Platform (partially):<br><br>810 nm Diode Laser System:<br>• Incision, excision, vaporization, ablation and coagulation of oral soft tissues including the following:<br>○ Gingival troughing for crown impression<br>○ Gingivectomy<br>○ Gingivoplasty<br>○ Gingival incision and excision<br>○ Hemostasis and coagulation<br>○ Excisional and incisional biopsies<br>○ Fibroma removal<br>○ Frenectomy and frenotomy<br>○ Oral papillectomies<br>○ Soft tissue crown lengthening<br>○ Treatment of aphthous ulcers<br>○ Treatment of herpetic lesions<br>• Periodontology: |

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| | | | ○ Laser soft tissue curettage<br>○ Laser removal of diseased, infected, inflamed and necrosed soft tissue within the perio-dontal pocket<br>• Cosmetic Dentistry:<br>○ Laser-assisted bleaching/whitening of the teeth<br>○ Light activation for bleaching materials for teeth whitening<br>• Implant recovery<br>• Surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or co-agulation of soft tissues in medical specialties including dermatology, dentistry, gastroenterology, general surgery, neurosurgery, otolaryngology, ophthalmology, and pulmonology<br><br>980 nm Diode Laser:<br>• Gingival troughing<br>• Crown lengthening<br>• Gingivoplasty<br>• Coagulation<br>• Hemostasis of donor site<br>• Implant recovery<br>• Implant uncovery<br>• Soft tissue curettage<br>• Sulcular debridement |

| | | | |
|---|---|---|---|
| | | | • Biopsy<br>• Frenectomy<br>• Operculectomy<br>• Exposure of unerupted teeth<br>• Pulpotomy<br>• Treatment of aphthous ulcers<br>• Excision of lesions<br>• Light activation of bleaching materials for teeth whitening<br>• Surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or co-agulation of soft tissues in medical specialties including dermatology, dentistry, gastroenterolo-gy, general surgery, genitourinary, gynecology, neurosurgery, otolaryngology, orthopedics, oph-thalmology, pulmonology, and thoracic surgery. |
| **Use of device** | RX only | RX only | RX only |
| **Laser type** | Diode laser | Diode laser | Diode laser |
| **Laser power** | 810nm: Up to 8 W<br>980nm: Up to 12 W | 810nm: Up to 7 W<br>980nm: Up to 9 W | 810nm: Up to 8 W<br>980nm: Up to 12 W |
| **Wavelength** | 810nm, 980nm | 810nm, 980nm, 1064nm | 810nm, 980nm |
| **Laser class** | 4 | 4 | 4 |
| **Operation Mode** | Continuous wave, pulsed, single pulse | Continuous wave, pulsed, single pulse | Continuous wave, pulsed, single pulse |
| **Pulse length / duration** | 100µs – 45s | 2ms – 30s | 100 µs to 60 s |
| **Pulse frequency** | 0.01 – 5000 Hz | 0.016 – 250 Hz | 0.008 Hz to 5000 Hz |
| **Aiming beam** | 532nm or 650nm @ <1mW | 650nm @ <2mW | Laser diode 650 nm or 532 nm ; < 1 mW |
| **Cooling** | Air | Air | Air |

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|---|---|---|---|
| **Delivery devices and accessories** | Optical fibers 300µm, 400µm and 600µm with or without hand pieces | Optical fibers 200µm, 300µm, 400µm and 600µm with or without hand pieces | 300 µm, 400 µm or 600 µm bare fiber with or without handpiece |
| **User interface** | Touchscreen and buttons | Display with rotary knob | Touch screen control |
| **Main power supply** | 100V-240V, 50Hz/60Hz or battery powered | 100-240 VAC, 50/60Hz or battery powered | 100-240 VAC, 50/60Hz or battery powered |
| **Dimensions** | Closed stand:<br>H 19,2 cm / W 14,2 cm / D 10,2 cm<br>Opened Stand:<br>H 17,4 cm / W 14.2 cm / D 16.3 cm | Closed stand:<br>H 21,1 cm / W 11,9 cm / D 10 cm<br>Opened stand:<br>H 18,5 cm / W 11,9 cm / D 19,2 cm | H 17.4 cm / W 14.2 cm / D 16.3 cm<br>with opened foot rest |
| **Weight** | 1,2 kg (2.64 pounds) | 1,2 kg (2.64 pounds) | 1,53 kg (3.37 pounds) |

**Performance testing:**

The FOX systems have been tested against

| Number of Standard | Name of Standard |
|---|---|
| IEC 60601-1:2005+ COR1:2006, COR2:2007, AMD1:2012 | Medical electrical equipment Part 1: General requirements for basic safety and essential performance |
| IEC 60825-1:2014 (Third Edition) | Safety of Laser Products – Part 1: Equipment classification and requirements |
| EN 60601-1-2:2014 (Forth Edition) | Medical electrical equipment Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility – Requirements and tests. |
| IEC 60601-2-22:2007 (Third Ed.) +A1:2012<br>for use in conjunction with IEC 60601-1:2005 (Third Ed.) + A1:2012 | Medical electrical equipment Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment |
| IEC 60601-1-6:2010/ AMD1:2013<br>for use in conjunction with IEC 62366-1;2015, AMD1:2020 & IEC 60601-1:2005, AMD1:2012, AMD2:2020 | Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability |
| IEC 62304:2006 + A1:2015 | Medical device software – Software life cycle process |

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**Substantial Equivalence statement and conclusion**

All predicate devices as well as the device under evaluation share the same wavelengths (810nm and 980nm). The wavelength is the main characteristic influencing the tissue interactions as the interaction with tissue is based on the absorption of the radiation in the corresponding chromophores. All tests conducted were done in continuous wave which can be seen as worst-case-scenario as in continuous wave the highest energy is applied. Tests for validation have also been performed for different power outputs and pulse settings.

The facts mentioned above show that the power difference between the predicate (810nm: 0,1W - 7W; 980nm: 0,1W - 9W) and the device under evaluation (810nm: 0,1W - 8W; 980nm: 0,1W - 12W) does not absolutely affect the extent of incision depth and thermal tissue damage. Power alone or pulse length alone do not alter the tissue effect because for every pulse the power is set with a pulse length. These parameters, power and pulse length, equal the pulse energy when multiplied.

In addition, the predicate device XPulse Pro Laser Platform from Fotona with K-Number K202991 shares the same power output as well as similar design and functional features and therefore is equivalent with the device under evaluation.

Based to above summary, we conclude that the subject devices are as safe and effective as the predicate devices.

Animal or clinical studies: None