June 22, 2021

Fotona d.o.o.
Marko Berdajs
Quality Assurance and Regulatory Affairs Manager
Stegne 7
Ljubljana, 1000
Slovenia

Re: K202991
Trade/Device Name: Fotona XPulse Pro Laser Platform
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: September 30, 2020
Received: September 30, 2020

Dear Marko Berdajs:

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,

Purva Pandya
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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202991

Device Name
XPulse Pro Laser Platform

Indications for Use *(Describe)*

810 nm Diode Laser System:

- Incision, excision, vaporization, ablation and coagulation of oral soft tissues including the following:
  - Gingival troughing for crown impression
  - Gingivectomy
  - Gingivoplasty
  - Gingival incision and excision
  - Hemostasis and coagulation
  - Excisional and incisional biopsies
  - Fibroma removal
  - Frenectomy and frenotomy
  - Oral papillectomies
  - Soft tissue crown lengthening
  - Treatment of aphthous ulcers
  - Treatment of herpetic lesions
- Periodontology:
  - Laser soft tissue curettage,
  - Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Cosmetic Dentistry:
  - Laser-assisted bleaching/whitening of the teeth,
  - Light activation for bleaching materials for teeth whitening
- Implant recovery
- 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

810 nm Diode Laser Module:

- Incision, excision, vaporization, ablation and coagulation of oral soft tissues including the following:
  - Gingival troughing for crown impression
  - Gingivoplasty
  - Soft tissue crown lengthening
  - Treatment of aphthous ulcers
  - Treatment of herpetic lesions

810 nm Diode Laser System & Module in therapy:

- 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.

980 nm Diode Laser:

- Gingival troughing
- Crown lengthening
- Gingivoplasty
- Coagulation

- Hemostasis of donor site
- Implant recovery
- Implant uncovery
- Soft tissue curettage
- Sulcular debridement
- Biopsy
- Frenectomy
- Operculectomy
- Exposure of unerupted teeth
- Pulpotomy
- Treatment of aphthous ulcers
- Excision of lesions
- Light activation of bleaching materials for teeth whitening
- 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.

445 nm Diode Laser:

- 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 K202991

SUBMITTER'S INFORMATION

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Date: June 21, 2021

DEVICE INFORMATION

Device Trade Name: **Fotona XPulse Pro Laser Platform**

Common name: Medical Laser System

Classification name: GEX-Powered Laser Surgical Instrument, General and Plastic Surgery
21 CFR 878.4810, Class II

Product Code: GEX

PREDICATE DEVICES

- Fotona SkyPulse Laser Platform (K193656)
- FOX 1-980, FOX Q-1064, FOX-Q-810 (K073322)
- Wolf445nm (K192272)
- SIROLaser Blue (K180044)
- XD Diode Laser System (K083034)

DEVICE DESCRIPTION

The Fotona XPulse Pro Laser Platform is a multi-application, multi-technology platform that supports the diode laser technology. A diode aiming beam is combined with all therapeutic laser beams. The combined therapeutic and aiming beams are guided through an optical fiber delivery system to an optical handpiece or to the bare fiber distal end.

The Fotona XPulse Pro Laser Platform consists of a console, a footswitch and attachable laser modules. Output parameters and other system features are controlled from the touch-screen control panel on the console, which provides an interface to the system micro-controller through an LCD touch-screen.

A diode aiming beam is combined with all therapeutic laser beams. The combined therapeutic and aiming beams are guided through an optical fiber delivery system to an optical handpiece or to the bare fiber distal end. The following wavelengths are currently available with the XPulse platform: 445 nm, 810 nm and 980 nm.

Following handpieces are to be used with Fotona Xpulse Pro Laser Platform: R21-SHP, R26 (variants: black, green, blue, silver and red), R24, R30, Genova and MarcCo (variants S, M & L).

INTENDED USE

810 nm Diode Laser System:

- Incision, excision, vaporization, ablation and coagulation of oral soft tissues including the following:
  - Gingival troughing for crown impression
  - Gingivectomy
  - Gingivoplasty
  - Gingival incision and excision
  - Hemostasis and coagulation
  - Excisional and incisional biopsies
  - Fibroma removal
  - Frenectomy and frenotomy
  - Oral papillectomies
  - Soft tissue crown lengthening
  - Treatment of aphthous ulcers
  - Treatment of herpetic lesions
- Periodontology:
  - Laser soft tissue curettage,
  - Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Cosmetic Dentistry:
  - Laser-assisted bleaching/whitening of the teeth,
  - Light activation for bleaching materials for teeth whitening
- Implant recovery
- 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

810 nm Diode Laser Module:

- Incision, excision, vaporization, ablation and coagulation of oral soft tissues including the following:
  - Gingival troughing for crown impression
  - Gingivoplasty
  - Soft tissue crown lengthening
  - Treatment of aphthous ulcers
  - Treatment of herpetic lesions

810 nm Diode Laser System & Module in therapy:

- 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.

980 nm Diode Laser:

- Gingival troughing
- Crown lengthening
- Gingivoplasty
- Coagulation
- Hemostasis of donor site
- Implant recovery
- Implant uncovery
- Soft tissue curettage
- Sulcular debridement
- Biopsy
- Frenectomy
- Operculectomy
- Exposure of unerupted teeth
- Pulpotomy
- Treatment of aphthous ulcers
- Excision of lesions
- Light activation of bleaching materials for teeth whitening
- 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.

445 nm Diode Laser:

- Incision/excision, vaporization, ablation, hemostasis and coagulation of soft tissue

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Fotona XPulse Pro Laser Platform has either identical or similar applicable technological and design characteristics (design, chemical composition, energy source, wavelength, active medium, power supply, beam delivery, controls, housing) as the previously cleared Fotona SkyPulse Laser Platform (K193656), FOX 1-980, FOX Q-1064, FOX-Q-810 (K073322), Wolf445nm (K192272), XD Diode Laser System (K083034) and SIROLaser Blue (K180044).

The output characteristics of the proposed device are similar to those of the predicate devices for the proposed intended use. All of the devices utilize class I aiming beams that pose a minimal hazard to the user when the devices are used properly. All systems are microprocessor controlled devices. The microprocessor control regulates normal operation, permits parameter selection and avoids hazard incidence.

A comparison of the technical specifications of the XPulse Laser platform with the previously cleared devices is provided in tabels below:

Table 1: Comparison table of the technical specifications of Fotona XPulse Pro Laser Platform with the previously cleared devices for the wavelength of 810 nm.

	XD Diode Laser System (K083034)	**Fotona SkyPulse Laser Platform** (K193656)	**Fotona XPulse Pro Laser Platform** (this submission)
Energy source	Diode	Diode	Diode
Wavelength	810 ± 10 nm	808 nm	810 nm
Power	Up to 7 W	0.1-33 W	Up to 8 W (system) Up to 1.5 W (module)
Pulse width	0.025 – 25 ms; CW	10 ms – 10 s; CW	20 µs to 30 s, CW
Repetition rate	CW or 20 Hz – 10 kHz	CW or up to 100 Hz	CW, 0.1 Hz to 200 Hz
Delivery system	Contact and non-contact handpieces connected to the system via fiber	Contact and non-contact handpieces connected to the system via fiber	Contact and non-contact handpieces connected to the system via fiber
User interface	Button control	Touch screen control	Touch screen control

Table 2: Comparison table of the technical specifications of Fotona XPulse Pro Laser Platform with the previously cleared devices for the wavelength of 980 nm.

	Fotona SkyPulse Laser Platform (K193656)	**Fotona XPulse Pro Laser Platform** (this submission)
Energy source	Diode	Diode
Wavelength	980 nm	980 nm
Aiming beam	Laser diode 635 nm/650 nm (red) ; < 1 mW	Laser diode 650 nm or 532 nm ; < 1 mW
Power range	Up to 35 W	Up to 12 W
Pulse width	10 ms – 10 s; CW	100 µs to 60 s, CW
Repetition rate	CW or up to 100 Hz	CW, 0.1 Hz to 200 Hz
Delivery system	Contact and non-contact handpieces connected to the system via fiber	Contact and non-contact handpieces connected to the system via fiber
User interface	Touch screen control	Touch screen control

Table 3: Comparison table of the technical specifications of Fotona XPulse Pro Laser Platform with the previously cleared device for the wavelength of 445 nm.

	Primary Predicate Device	**Reference Predicate device**	**Subject Device**
	Wolf 445nm (K192272)	**SIROLaser Blue** (K180044)	**Fotona XPulse Pro Laser Platform** (This submission)
Indication	The Wolf 455 nm is intended for use in incision, excision, vaporization, ablation, hemostasis and coagulation of soft tissue	SIROLaser Blue is intended for inta and extra oral surgery including incision, excision, hemostasis, coagulation & vaporization of soft tissue	Incision/excision, vaporization, ablation, hemostasis and coagulation of soft tissue
Wavelength	445 nm	445 nm	445 nm
Power	0.5-10 W	0.2 - 3 W	Up to 4 W
Repetition rate	≤ 4 Watt: 0.01 Hz to 500 Hz and CW > 4 Watt: 0.02 Hz to 6.6 Hz and CW	1 Hz to 10 kHz	CW, 0.1 Hz to 200 Hz
Delivery system	Optical fibers 300 µm, 400 µm and 600 µm with or without handpieces	Delivery devices, fibers 200 mm, 320 mm	300 µm, 400 µm or 600 µm bare fiber with or without handpiece R21 and R21-SHP

TESTING

Clinical testing: No clinical testing was needed.

Fotona XPulse Pro Laser Platform is designed, tested and will be manufactured in accordance with both mandatory and voluntary standards:

ISO 14971:2007
Medical devices — Application of risk management to medical devices

IEC 60601-1:2005 + A1:2012
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests.

IEC 62304:2006 + A1:2015
Medical device software - Software life-cycle processes.

IEC 60601-1-6:2010 + A1:2013
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

IEC 62366:2007 + A1:2014
Medical devices - Application of usability engineering to medical devices.

IEC 60601-2-22:2007 + A1:2012
Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

Laboratory testing was conducted to support that the proposed Xpulse Pro Laser Platform meets all design specifications and that it is substantially equivalent to the predicate devices.

STATEMENT OF SUBSTANTIAL EQUIVALENCE

The XPulse Pro Laser Platform shares the same indications for use, similar design and functional features with predicate devices, and therefore Fotona believes that its XPulse Pro Laser Platform is substantially equivalent to the Fotona SkyPulse Laser Platform (K193656), Fox Q-810, Q-980 and Q-1064(K073322),Wolf 445nm (K192272), XD Diode Laser System (K083034) and SIROLaser Blue (K180044).

Based on its technical characteristics, performance test data, and its indications for use, the Fotona XPulse Pro Laser Platform is found to be substantially equivalent to the predicate devices.