October 12, 2022

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

Re: K221712
Trade/Device Name: Fotona XPulse Laser System Family (XPulse 1064 nm, XPulse 810 nm, XPulse 980 nm)
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: June 10, 2022
Received: June 13, 2022

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,

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221712

Device Name
Fotona XPulse Laser System Family

Indications for Use *(Describe)*

1064 nm Diode Laser in dentistry:
• Excisional and incisional biopsies
• Excision and vaporization of herpes simplex I and II
• Frenectomy and frenotomy
• Gingivectomy
• Gingivoplasty
• Gingival incision and excision
• Hemostasis
• Implant recovery
• Operculectomy
• Pulpotomy and pulpotomy as an adjunct to root canal therapy
• Removal of filling material such as gutta percha or resin as adjunct treatment during root canal therapy
• Sulcular debridement or soft tissue curettage (removal of 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)
• Treatment of aphthous ulcers and herpetic lesions

1064 nm Diode Laser in dermatology and other surgical areas:
• General surgery indications: surgical incision, excision, vaporization and coagulation of soft tissue. All soft tissue is included, striated and smooth tissue, muscle, cartillage, meniscus, mucous membrane, lymph vessels and nodes, organs and glands, fibroma removal.
• Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including: Matrixectomy, Periungual and subungual warts, Plantar warts, Radical nail excision, Neuromas.
• Temporary increase of clear nail in patients with onychomycosis (e.g. dermatophytes Trichophyton rubrum and T mentagrophytes and/or yeasts Candida albicans, etc.)

1064 nm Diode Laser in therapy:
• Temporary relief of muscle and joint pain and stiffness, arthritis pain or muscle spasm, temporary increase in local blood circulation and/or promoting relaxation of muscle.

810 nm Diode Laser in dentistry:
• 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
• Oral/Maxillofacial Indications: Incision, excision, vaporization, ablation and/or coagulation of soft tissue
◦ 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

810 nm Diode Laser 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 in dentistry:
• 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
• Gingival troughing
• Crown lengthening
• Gingivoplasty
• Coagulation
• Implant uncovery
• Implant recovery
• Soft tissue curettage
• Sulcular debridement
• Biopsy
• Frenectomy
• Hemostasis of donor site
• Operculectomy
• Exposure of unerupted teeth
• Pulpotomy
• Treatment of aphthous ulcers
• Excision of lesions
• Light activation of bleaching materials for teeth whitening

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

SUBMITTER'S INFORMATION

Submitter: Fotona d.o.o.
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Date: June 10, 2022

DEVICE INFORMATION

Device Trade Name: **Fotona XPulse Laser System Family**

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)
- Fotona XPulse Pro Laser Platform (K202991)
- Fotona LightWalker Laser System Family (K202985)

DEVICE DESCRIPTION

The Fotona XPulse Laser System Family is a multi-application, multi-technology laser system family 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 Laser System Family consists of a console and a footswitch. 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 System Family: 810 nm, 980 nm and 1064 nm.

The following handpieces are to be used with Fotona XPulse Laser System Family: R21 (variants C2, C3, SHP and EHP), R26 (variants: black, green, blue, silver and red), Genova- and MarcCo (variants S, M and L).

INDICATIONS FOR USE

1064 nm Diode Laser in dentistry:

- Excisional and incisional biopsies
- Excision and vaporization of herpes simplex I and II
- Frenectomy and frenotomy
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis
- Implant recovery
- Operculectomy
- Pulpotomy and pulpotomy as an adjunct to root canal therapy
- Removal of filling material such as gutta percha or resin as adjunct treatment during root canal therapy
- Sulcular debridement or soft tissue curettage (removal of 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)
- Treatment of aphthous ulcers and herpetic lesions

1064 nm Diode Laser in dermatology and other surgical areas:

- General surgery indications: surgical incision, excision, vaporization and coagulation of soft tissue. All soft tissue is included, striated and smooth tissue, muscle, cartillage, meniscus, mucous membrane, lymph vessels and nodes, organs and glands, fibroma removal.
- Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including: Matrixectomy, Periungual and subungual warts, Plantar warts, Radical nail excision, Neuromas.
- Temporary increase of clear nail in patients with onychomycosis (e.g. dermatophytes Trichophyton rubrum and T mentagrophytes and/or yeasts Candida albicans, etc.)

1064 nm Diode Laser in therapy:

- Temporary relief of muscle and joint pain and stiffness, arthritis pain or muscle spasm, temporary increase in local blood circulation and/or promoting relaxation of muscle.

810 nm Diode Laser in dentistry:

- 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
- Oral/maxillofacial Indications: Incision, excision, vaporization, ablation and coagulation of oral soft tissue
  - 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

810 nm Diode Laser 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:

- 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
- Gingival troughing
- Crown lengthening
- Gingivoplasty
- Coagulation
- Implant recovery
- Implant uncovery
- Soft tissue curettage
- Sulcular debridement
- Biopsy
- Frenectomy
- Hemostasis of donor site
- Operculectomy
- Exposure of unerupted teeth
- Pulpotomy

- Treatment of aphthous ulcers
- Excision of lesions
- Light activation of bleaching materials for teeth whitening

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Fotona XPulse Laser System Family 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), Fotona LightWalker Laser System Family (K202985) and Fotona XPulse Pro Laser Platform (K202991).

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 System Family with the previously cleared devices is provided in tables below:

Table 1: Comparison table of the technical specifications of Fotona XPulse Laser System Family with the previously cleared devices for the wavelength of 1064 nm.

	Fotona SkyPulse Laser Platform (K193656)	**Fotona LightWalker Laser System Family** (K202985)	**XPulse Laser System Family** (This submission)
Energy source	Solid state diode	Solid state Nd:YAG	Solid state diode
Wavelength	1064 nm	1064 nm	1064 nm
Aiming beam	Laser diode 635 nm/650 nm (red); < 1 mW	Laser diode 635 nm/650 nm (red) or 520-532 nm (green); < 1 mW	Laser diode 532 nm (green); < 1 mW
Power	up to 32 W	Up to 30 W	up to 10 W
Pulse width	10 ms – 10 s/CW	0.1 - 25 ms	0.1 ms - 45 s/CW
Repetition rate	up to 100 Hz/CW	Up to 100 Hz	up to 200 Hz/CW
Delivery system	Contact and non-contact handpieces connected to the system via fiber delivery	Contact and non-contact handpieces connected to the system via fiber delivery	Contact and non-contact handpieces connected to the system via fiber delivery
User interface	Touch screen control	Tocuh screen control	Touch screen control

Table 2: Comparison table of the technical specifications of Fotona XPulse Laser System Family with the previously cleared devices for the wavelength of 810 nm.

	Fotona SkyPulse Laser Platform (K193656)	**Fotona XPulse Pro Laser Platform** (K202991)	**XPulse Laser System Family** (This submission)
Energy source	Solid state diode	Solid state diode	Solid state diode
Wavelength	808 nm	810 nm	810 nm
Aiming beam	Laser diode 635 nm/650 nm (red); < 1 mW	Laser diode 532 nm/650 nm (red); < 1 mW	Laser diode 532 nm (green); < 1 mW
Power	up to 33 W	up to 8 W	up to 8 W
Pulse width	10 ms – 10 s/CW	0.1 ms – 60 s/CW	0.1 ms - 45 s/CW
Repetition rate	up to 100 Hz/CW	up to 200 Hz/CW	up to 200 Hz/CW
Delivery system	Contact and non-contact handpieces connected to the system via fiber	Contact and non-contact handpieces connected to the system via fiber delivery	Contact and non-contact handpieces connected to the system via fiber delivery
User interface	Touch screen control	Touch screen control	Touch screen control

Table 3: Comparison table of the technical specifications of Fotona XPulse Laser System Family with the previously cleared devices for the wavelength of 980 nm.

	Fotona SkyPulse Laser Platform (K193656)	**Fotona XPulse Pro Laser Platform (K202991)**	**XPulse Laser System Family** (This submission)
Energy source	Solid state diode	Solid state diode	Solid state diode
Wavelength	980 nm	980 nm	980 nm
Aiming beam	Laser diode 635 nm/650 nm (red); < 1 mW	Laser diode 532 nm/650 nm (red); < 1 mW	Laser diode 532 nm (green); < 1 mW
Power range	up to 35 W	up to 12 W	up to 12 W
Pulse width	10 ms – 10 s/CW	0.1 ms – 60 s/CW	0.1 ms - 45 s/CW
Repetition rate	up to 100 Hz	up to 200 Hz/CW	up to 200 Hz/CW
Delivery system	Contact and non-contact handpieces connected to the system via fiber	Contact and non-contact handpieces connected to the system via fiber delivery	Contact and non-contact handpieces connected to the system via fiber delivery
User interface	Touch screen control	Touch screen control	Touch screen control

TESTING

Clinical testing: No clinical testing was needed.

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

ISO 14971:2019
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 compatibility - Requirements and tests.

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.

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 60601-1-9:2007 + A1:2013
Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral standard: Requirements for environmentally conscious design.

IEC 60825-1:2014
Safety of laser products - Part 1: Equipment classification and requirements.

IEC 62366-1:2015 (state-of-the-art edition)
Medical devices - Part 1: Application of usability engineering to medical devices

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

Laboratory testing was conducted to support that the proposed XPulse Laser System Family meets all design specifications and that it is substantially equivalent to the predicate devices.

STATEMENT OF SUBSTANTIAL EQUIVALENCE

The XPulse Laser System Family shares the same intended use, similar design and functional features with predicate devices, and therefore Fotona believes that its XPulse Laser System Family is substantially equivalent to the Fotona SkyPulse Laser Platform (K193656), Fotona LightWalker Laser System Family (K202985) and Fotona XPulse Pro Laser Platform (K202991).

Based on its technical characteristics, performance test data, and its intended use, the Fotona XPulse Laser System Family is found to be substantially equivalent to the predicate devices.