March 25, 2020

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

Re: K193661
Trade/Device Name: LightWalker Laser System Family
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: December 24, 2019
Received: December 30, 2019

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 post-marketing 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

Indications for Use

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

510(k) Number *(if known)*
K193661

Device Name
LightWalker Laser System Family

Indications for Use *(Describe)*
Er:YAG laser (2940 nm wavelength) in dentistry:

- Intra-oral soft tissue surgery (incision, excision, ablation, coagulation)
- Leukoplakia
- Pulpotomy as adjunct to root canal retreatment
- Pulp extirpation
- Removal of fibromae
- Removal of granulated tissue
- Caries removal, cavity preparation, enamel roughening
- Sulcular debridement
- Tooth preparation to obtain access to root canal, root canal debridement and cleaning, root canal preparation including enlargement
- Cutting, shaving, contouring and resection of oral osseous tissue (bone)
- Osteotomy, osseous crown lengthening, osteoplasty
- Apicectomy surgery
- Removal of subgingival calculi in periodontal pockets with periodontitis by closed or open curetage
- Laser removal of porcelain and ceramic crowns and veneers
- Flap preparation – incision of soft-tissue to prepare a flap and expose the bone
- Cutting bone to prepare a window access to the apex (apices) of the root(s)
- Root-end preparation for retrofill amalgam or composite
- Full thickness flap
- Partial thickness flap
- Split thickness flap
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining junctional epithelium
- Excisional and incisional biopsies
- Flap preparation – incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions)
- Frenectomy and frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Implant recovery
- Root canal debridement and cleaning
- Soft tissue crown lengthening
- Laser root canal disinfection after endodontic treatment

Er:YAG laser (2940 nm wavelength) in dermatology and other surgical areas:

• Dermatology and Plastic Surgery Indications: Epidermal nevi, actinic cheilitis, verrucae, skin tags, keratoses and skin resurfacing
• ENT Surgery Indications: ENT lesions, cysts, polyps, hyperkeratosis, oral leukoplakia
• Oral/Maxillofacial Indications: Oral and glossal lesions, gingivectomy
• General Surgery Indications: Surgical incision/excision, vaporization and coagulation of soft tissue during any general surgery application where skin incision, tissue dissection, excision of lesions, complete or partial resection of internal organs, lesions, tissue ablation and vessel coagulation
• Podiatry Indications: Warts, plantar verrucae, large mosaic verrucae, matrixectomy
• Ophtalmology Indications: Soft tissue surrounding the eye
• Gynecology Indications: Herpes simplex, endometrial adhesion, CIN (Cervical intraepithelial neoplasia), cysts, condiloma
• Genitourinary Indications: Lesions of the external genitalia, urethra and anus, penis, scrotum and urethra, vulvar lesions, polyps and familial polyps of the colon

Nd:YAG laser (1064 nm wavelength) in dentistry:

• Excisional and incisional biopsies
• Excision and vaporization of herpes simplex I and II
• Exposure of unerupted teeth
• Fibroma removal
• Frenectomy and frenotomy
• Gingival troughing for crown impressions
• Gingivectomy
• Gingivoplasty
• Gingival incision and excision
• Hemostasis
• Implant recovery
• Incision and drainage of abscess
• Laser assisted uvulopaletoplasty (LAUP)
• Operculectomy
• Oral papillectomies
• Pulpotomy and pulpotomy as an adjunct to root canal therapy
• Reduction of denture hyperplasia
• Reduction of gingival hypertrophy
• Removal of filling material such as gutta percha or resin as adjunct treatment during root canal therapy
• Removal of post-surgical granulations
• Soft tissue crown lengthening
• 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)
• Tissue retraction for impression
• Treatment of aphtous ulcers
• Vestibuloplasty
• Laser assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium)
• Periodontal regeneration – true regeneration of the attachment apparatus (new cementum, new periodontal ligament, and new alveolar bone) on a previously diseased root surface

Nd:YAG laser (1064 nm wavelength) in dermatology and other surgical areas:

• Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin*
• Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemangiomae, warts, telangiectasiae, rosacea, venus lake, leg veins and spider veins
• Treatment of wrinkles
• Treatment of mild to moderate inflammatory acne vulgaris
• 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.)
Nd:YAG laser (1064 nm wavelength) 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.

*Note: Permanent hair reduction is defined as the long-term, stable redction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

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. Stegne 7 1000 Ljubljana, Slovenia Phone: +386 1 5009 100 Fax: +386 1 5009 200
Contact Person:	Marko Berdajs, Quality Assurance and Regulatory Affairs Manager Phone: + 386 1 5009 119 E-mail: marko.berdajs@fotona.com
Date:	March 24, 2020

DEVICE INFORMATION

Device Trade Name:	**LightWalker 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 LightWalker Laser System Family (K191554)
- Biolase WaterLase Laser System Family (K190319)
- Fotona Dynamis Pro Laser System Family (K182088)

DEVICE DESCRIPTION

The device is Fotona LightWalker laser system family (same as K191554). It is based on Er:YAG (2940 nm) and Nd:YAG (1064 nm) laser technology. It combines two flashlamp-pumped laser sources in one housing, with optical cavities containing the Er:YAG and Nd:YAG crystals. A diode aiming beam is combined with both therapeutic laser beams. The combined therapeutic and aiming beams are guided through an articulated arm to an optical handpiece (in the case of the Er:YAG laser), or, in the case of the Nd:YAG laser, through an optical fiber delivery system to an optical handpiece or to the bare fiber distal end.

The Er:YAG laser is capable of delivering up to 1.5 J of laser energy in pulses with durations of 50 - 1000 μs and frequencies (repetition rates) of up to 50 Hz. The maximum average output power is 20 W. The laser is intended to be used for incision/excision, cutting, ablation, vaporization and coagulation of soft and hard tissue in dentistry, dermatology and other surgical areas.

The Nd:YAG laser is capable of delivering up to 10 J of energy with pulse durations from 0.1-25 ms, and frequencies of up to 100 Hz. For dental indications it is capable of delivering laser pulses with durations of up to 650 μs, frequencies (repetition rates) of up to 100 Hz and a maximum output power of 15 W. The laser is intended to be used for various intra oral treatments in dentistry, and for various surgical and aesthetic applications in dermatology and other surgical areas.

INTENDED USE

2940 nm Er:YAG Laser in dentistry:

- Intra-oral soft tissue surgery (incision, excision, ablation, coagulation)
- Leukoplakia
- Pulpotomy as adjunct to root canal retreatment
- Pulp extirpation
- Removal of fibromae
- Removal of granulated tissue
- Caries removal, cavity preparation, enamel roughening
- Sulcular debridement
- Tooth preparation to obtain access to root canal, root canal debridement and cleaning, root canal preparation including enlargement
- Cutting, shaving, contouring and resection of oral osseous tissue (bone)
- Osteotomy, osseous crown lengthening, osteoplasty
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- Laser root canal disinfection after endodontic treatment

2940 nm Er:YAG Laser in dermatology and other surgical areas

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Nd:YAG laser (1064 nm wavelength) in dentistry:

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- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris
- 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.
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- Temporary increase of clear nail in patients with onychomycosis (e.g. dermatophytes Trichophyton rubrum and T mentagrophytes and/or yeasts Candida albicans, etc.)

Nd:YAG laser (1064 nm wavelength) 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.

*Note: Permanent hair reduction is defined as the long-term, stable redction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Fotona LightWalker Laser System Family has either identical or similar applicable technological and design characteristics (design, chemical composition, energy source, wavelength, active medium, cooling system, power supply, beam delivery, controls, housing) as the previously cleared Fotona LightWalker Er:YAG/Nd:YAG Laser System Family (K191554), Biolase WaterLase Laser System Family (K190319) and Fotona Dynamis Pro Laser System Family (K182088). 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. All systems utilize an internal closed loop water-air heat exchanger circuit for optimal thermal control of the laser cavity.

A comparison of the technical specifications for the intended use of the LightWalker Laser System Family with the previously cleared devices is provided in Table 1.

Table 1: Comparison table of the technical specifications of Fotona LightWalker Laser System Family with previously cleared devices.

	LightWalker Laser System Family (K191554)	**WaterLase Laser System Family** (K190319)	**Dynamis Pro Laser System Family** (K182088)	**LightWalker Laser System Family** (this submission)
Energy source	Solid state Er:YAG	Solid state Er,Cr:YSGG	Solid state Er:YAG	Solid state Er:YAG
Wavelength	2940 nm	2780 nm	2940 nm	2940 nm
Aiming beam	Laser diode 635 nm/650 nm (red) or 520-532 nm (green); < 1 mW	Laser diode 635 nm (red) ; < 1 mW	Laser diode 635 nm/650 nm (red) ; < 1 mW	Laser diode 635 nm/650 nm (red) or 520-532 nm (green); < 1 mW
Power	Up to 20 W	Up to 10 W	Up to 20 W	Up to 20 W
Energy per pulse	Up to 1500 mJ	Up to 600 mJ	Up to 3000 mJ	Up to 1500 mJ
Pulse width	50-1000 µs	60-700 µs	50-1500 µs	50-1000 µs
Repetition rate	Up to 50 Hz	Up to 100 Hz	Up to 50 Hz	Up to 50 Hz
Delivery system	Articulated arm	Fiber delivery	Articulated arm	Articulated arm
User interface	Touch screen control	Touch screen control	Touch screen control	Touch screen control

TESTING

Clinical testing:

No clinical testing was needed.

Fotona LightWalker laser system family is designed, tested and will be manufactured in accordance with both mandatory and voluntary standards

EN 60601-1:2006 + A1:2013 *
Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance.

EN 60601-1-2:2015♦
Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

EN 60601-2-22:2013 *♦
Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

EN 60601-1-6:2010 + A1:2015 *
Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

EN 62366:2008 + A1:2015 *
Medical devices - Application of usability engineering to medical devices.

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

EN ISO 14971:2012
Medical devices - Application of risk management to medical devices.

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

EN ISO 17664:2004
Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

EN ISO 10993-1:2009
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

* For international compliance see CB Scheme standards
♦ The standard EN 60601-2-22:2013 and EN 60601-1-2:2015 have been published but not harmonized yet. It is however our decision to follow the current state of the art assuming the newer standards assure a higher level of safety.

CB Scheme standards:

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

IEC 62366:2007 + A1:2014
Medical devices - 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 Fotona LightWalker laser system family meets all design specifications and that it is substantially equivalent to the predicate devices.

STATEMENT OF SUBSTANTIAL EQUIVALENCE

The LightWalker Laser System Family shares the same indications for use, similar design and functional features with predicate devices, and therefore Fotona believes that its LightWalker laser system family is substantially equivalent to the Fotona LightWalker Er:YAG/Nd:YAG Laser System Family **(**K191554), Biolase WaterLase Laser System Family (K190319) and Fotona Dynamis Pro Laser System Family (K182088).

Based on its technical characteristics, performance test data, and its indications for use as listed above, the Fotona LightWalker Laser System is found to be substantially equivalent to the predicate devices.