December 1, 2017

Fotona d.o.o.
Marko Berdajs
R&D Engineer
Stegne 7
Ljubljana, Si

Re: K172819
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: September 15, 2017
Received: September 18, 2017

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K172819

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

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;

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 imflamed 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, hemaongiomae, 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

The Fotona LightWalker Laser System Family is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T mentagrophytes, and/or yeasts Candida albicans, etc.).

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 Phone: + 386 1 5009 119 E-mail: marko.berdajs@fotona.com
Date:	September 15, 2017

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 Fidelis III Er:YAG/Nd:Y AG Laser System Family (K070355)
- PerioLase Nd: YAG Pulsed Dental Laser System (K151763)

DEVICE DESCRIPTION

The device is Fotona LightWalker laser system family (same as K121508). 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 hand piece (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 hand piece 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

a) The Fotona LightWalker Laser System Family and its accessories will be marketed for the following indications added in this submission:

Nd:YAG laser (l064 nm wavelength) in dentistry:

– Laser assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence oflongjunctional epithelium)

– Periodontal regeneration – true regeneration of the attachment apparatus (new cementum, new periodontal ligament, and new alveolar bone) on a previously diseased root surface.

b) Fotona LightWalker Laser System Family and its accessories will also be marketed for the following indications for use, already previously cleared under K121508:

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

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;

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 imflamed 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

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, hemaongiomae, 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:
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– Neuromas

The Fotona LightWalker Laser System Family is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T mentagrophytes, and/or yeasts Candida albicans, etc.).

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Fotona LightWalker Laser System Family has the same 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's LightWalker Laser System family Device (K121508) and the predicate devices Fotona Fidelis III Er:YAG/Nd: YAG Laser System (K070355**)** and PerioLase Nd:YAG Pulsed Dental Laser System (K151763). The output characteristics are for the intended use the same as those of the predicate devices. All lasers utilize class I aiming beams which pose no hazard to the user. 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. The risk and benefits for the Fotona LightWalker Laser System Family are identical to the predicate devices when used for similar clinical applications.

The indications for use required no changes to the device or software previously cleared to market, thus we believe LightWalker Laser System Family is substantially equivalent in terms of indications for use and technology based on technical characteristics to previously predicate devices.

A comparison of the technical specifications for the intended use of the LightWalker

Laser System Family with the previously cleared devices is provided in Tables 1 and 2.

Table 1:Indication for use: Laser assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium); Comparison of Fotona LightWalker Laser System Family with the predicate device: Fotona Fidelis III Laser System Family (K070355).

	TREATMENT PARAMETERS	
	Fotona Fidelis III Family (K070355)	**LightWalker Laser System Family** (K172819)
Wavelength	1064 nm	1064 nm
Contact part	Bare fiber	Bare fiber
Power	2 – 4 W	2- 4 W
Pulsewidth Mode	SP mode and LP mode	SP mode and LP mode*
Frequency	10 – 20 Hz	10 – 20 Hz
Fiber diameter	300 µm	300 µm

* SP and LP LightWalker's modes denote pulse durations 150 µs and 650 µs, respectively.

Table 2: Indication for use: Periodontal regeneration – true regeneration of the attachment apparatus (new cementum, new periodontal ligament, and new alveolar bone) on a previously diseased root surface; Comparison of Fotona LightWalker Nd:YAG with the predicate device: Periolase Nd:YAG Laser System (K151763).

	TREATMENT PARAMETERS	
	Millennium Periolase Nd:YAG (K151763)	**LightWalker Laser System Family** (K172819)
Wavelength	1064 nm	1064 nm
Contact part	Bare fiber	Bare fiber
Power	3 - 4 W	3 - 4 W
Pulsewidth	150 µs and 650 µs	150 µs and 650 µs
Frequency	20 Hz	20 Hz
Fiber diameter	360 µm - 400 µm	360 µm - 400 µm

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 Fidelis III Er:YAG/Nd:YAG Laser System Family (K070355) and PerioLase Nd: YAG Pulsed Dental Laser System (K151763).

The Fotona LightWalker Laser System Family is substantially equivalent in terms of indications for use and technology based on technical characteristics.

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 has been conducted to validate and verify that the proposed Fotona LightWalker laser system family meets all design specifications and is substantially equivalent to the predicate devices.