March 19, 2021

Fotona d.o.o.
Pucer Anja
Quality Assurance and Regulatory Affairs
Stegne 7
Ljubljana, SI-1000
Slovenia

Re: K202985
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 30, 2020
Received: September 30, 2020

Dear Pucer Anja:

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 and Part 809; 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202985

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 curettage;
• 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:
The LightWalker Er:YAG laser is intended for surgical incision/excision, cutting, ablation, vaporization and coagulation of soft and hard tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs, and glands.
• Dermatology and Plastic Surgery Indications: epidermal nevi, actinic cheilitis, verrucae, skin tags, keratoses and soft tissue resurfacing;
• ENT Surgery Indications: ENT lesions, cysts, polyps, hyperkeratosis, oral leukoplakia;
• Oral/Maxillofacial Indications: Oral and glossal lesions, gingivectomy;

• Uvulopalatoplasty by laser resurfacing
• 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;
• Dermatological procedures requiring resurfacing of soft tissue with Fotona FS-01 fractionated handpiece.

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 toothmobility);
• 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.);
• Endo Venous Laser Therapy of superficial incompetent tributary veins associated with varicose veins and varicosities.

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:	Dr. Pucer Anja Phone: + 386 1 5009 100 E-mail: anja.pucer@fotona.com
Date:	February 18, 2021

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

- LightWalker Laser System Family (K193661)
- Dynamis Pro Family (K182088)

DEVICE DESCRIPTION SUMMARY

The Fotona LightWalker Laser System Family 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 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 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/INDICATIONS FOR USE

The Fotona LightWalker Laser System Family and its accessories will be marketed for the following indications:

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 curettage;
- 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:

- The LightWalker Er:YAG laser is intended for surgical incision/excision, cutting, ablation, vaporization and coagulation of soft and hard tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs, and glands.
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- Dermatological procedures requiring resurfacing of soft tissue with Fotona FS-01 fractionated handpiece;

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;
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- Gingivoplasty;
- Gingival incision and excision;
- Hemostasis;
- Implant recovery;
- Incision and drainage of abscess;
- Laser assisted uvulopalatoplasty (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;
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- Tissue retraction for impression;
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- Vestibuloplasty;
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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;
- Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including: Matrixectomy, Periungual and subungual warts, Plantar warts, Radical nail excision, Neuromas;
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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.

INDICATIONS FOR USE COMPARISON

The indications for use from the predicate laser devices that are now included in the LightWalker Laser System Family do not raise new types of questions regarding safety and effectiveness. A new Uvulopalatoplasty by laser resurfacing indication for use with the Er:YAG laser output (2940 nm) has been introduced, based on the Laser assisted uvulopalatoplasty indication for use previously cleared for the primary predicate device with the Nd:YAG laser output (1064 nm).

TECHNOLOGICAL COMPARISON

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 Laser System Family (K193661) and Dynamis Pro Family (K182088). Four new handpieces have been introduced. The new handpieces offer new treatment options for specific indications for use that were previously cleared for the predicate devices. 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.

Table 1: Comparison table of the technical specifications of LightWalker Laser System Family with the primary predicate LightWalker Laser System Family (K193661) and the secondary predicate Dynamis Pro Family (K182088), which is the predicate for the newly submitted indications for use.

	LightWalker Laser System Family (K193661)		**Dynamis Pro Family (K182088)**		**LightWalker Laser System Family** (K202985)	
Energy source	Solid state Er:YAG	Solid state Nd:YAG	Solid state Er:YAG	Solid state Nd:YAG	Solid state Er:YAG	Solid state Nd:YAG
Wavelength	2940 nm	1064 nm	2940 nm	1064 nm	2940 nm	1064 nm
Aiming beam	Laser diode 635 nm/650 nm (red) or 520-532 nm (green); < 1 mW		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 15 W	Up to 20 W	Up to 80 W	Up to 20 W	Up to 30 W
Energy per pulse	Up to 1500 mJ	Up to 10 J	Up to 3000 mJ	Up to 50 J	Up to 1500 mJ	Up to 20 J
Pulse width	50-1000 µs	0.1 - 25 ms	100-1500 µs	0.1 - 50 ms	25-1000 µs	0.1 - 25 ms
Repetition rate	Up to 50 Hz	Up to 100 Hz	Up to 50 Hz	Up to 100 Hz	Up to 50 Hz	Up to 100 Hz
Delivery system	Articulated arm	Fiber	Articulated arm	Fiber	Articulated arm	Fiber
User interface	Touch screen control		Touch screen control		Touch screen control	

NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY AND CONCLUSIONS

Non-Clinical Summary:

The LightWalker Laser System Family has been evaluated via verification and validation tests and inspections for conformance to the applicable regulations and safety standards. The LightWalker Laser System is designed, tested and will be manufactured in accordance with both, mandatory and voluntary standards:

EN-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 disturbances - 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 17664:2017 Processing of health care products - Information to be provided by the medical

device manufacturer for the processing of medical devices

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

* state-of the-art amendment A1 published, but not harmonized yet

♦ The standard EN 60601-2-22:2013 has 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.

For international compliance see CB Scheme standards and ISO standards:
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 disturbances - 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 62366:2007 + A1:2014 Medical devices - Application of usability engineering to medical devices.
IEC 62304:2006 + A1:2015 Medical device software - Software life-cycle processes.

ISO standards:
ISO 14971:2007 Medical devices - Application of risk management to medical devices
ISO 17664:2004 * Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
ISO 17664:2017 (state-of-the-art edition)* Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
ISO 10993-1:2009 * Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-1:2018 (state-of-the-art edition)* Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
* With fulfilling the requirements of the latest standard edition, all requirements of previous standard edition are still fulfilled.

Clinical Summary:
Not Applicable.

CONCLUSIONS:

The LightWalker Laser System Family's indications for use and technological characteristics do not raise new types of questions regarding safety and efficacy when compared to the predicates. Based on its technical characteristics, design, functional features, performance test data, and its indications for use as listed above, the Fotona LightWalker Laser System Family is considered to be substatially equivalent to the predicate devices.