August 23, 2024

Fotona d.o.o.
Tina Bartolic
Quality Assurance and Regulatory Affairs Specialist
Stegne 7
Ljubljana,
Slovenia

Re: K242202
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: July 26, 2024
Received: July 26, 2024

Dear Tina Bartolic:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2024.08.23 11:27:11 -04'00'

Tanisha Hithe
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242202

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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SPECIAL 510(K) SUMMARY

1. SUBMITTER INFORMATION	
Applicant & OfficialCorrespondent	Ms. Tina Bartolic Quality Assurance and Regulatory Affairs Specialist Fotona d.o.o. Stegne 7, Ljublijana, Slovenia +38615009100 tina.bartolic@fotona.com
Date Prepared	August 12, 2024
2. DEVICE NAME	
Trade Name of the Device	LightWalker Laser System Family
Common Name:	LightWalker Laser System Family
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Regulation:	21 CFR 878.4810
Device Class:	Class II
Product Code:	GEX
Panel:	General and Plastic Surgery
3. PREDICATE DEVICEIDENTIFICATION	K202985 LightWalker Laser System Family
4. DEVICE DESCRIPTION:	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.
5. INDICATIONS FOR USE:	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;

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	• 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;

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	• 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;

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	• 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.

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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.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	LightWalker Laser System Family (K202985)		LightWalker Laser System Family (K242202- this submission)	
	Er:YAG	Nd:YAG	Er:YAG	Nd:YAG
Wavelength	2940 nm	1064 nm	2940 nm	1064 nm
Laser media	Flashlamp solid state Er:YAG rod	Flashlamp solid state Nd:YAG rod	Flashlamp solid state Er:YAG rod	Flashlamp solid state Nd:YAG rod
Output mode	Pulsed	Pulsed	Pulsed	Pulsed
Pulse energy	Up to 1.5 J	Up to 20 J	Up to 1.5 J	Up to 20 J
Pulsewidth	0.025 – 1 ms	0.1 – 25 ms	0.025 – 1 ms	0.1 – 25 ms
Repetition rate	Up to 50 Hz	Up to 100 Hz	Up to 50 Hz	Up to 100 Hz
Power	Up to 20 W	Up to 30 W	Up to 20 W	Up to 30 W
Beam Delivery	Articulated Arm	Fiber	Articulated Arm	Fiber
User Interface	Touchscreen	Touchscreen	Touchscreen	Touchscreen
Operating System	Windows	Windows	Linux	Linux
User Interface Screen Size	8.4"	8.4"	10.1"	10.1"

The subject and the predicate device have the same intended use, and have the same technological characteristics in terms of laser output parameters, as can be concluded from the above comparison table. Both devices use the same housing, laser sources, power supplies, cooling system and beam delivery system, the only difference being in the type of the operating system and in the size of the user interface screen. Based on its technical characteristics, design, functional features, performance test data, and its indications for use, the

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submitted device is considered to be substantially equivalent to the predicate device. Performance testing was conducted on the subject device, and it was established that the newly introduced features do not raise different questions of safety or effectiveness.	
7.SUMMARY OF NONCLINICAL TESTING:	Below is a list of the tests that were performed and successfully completed for the subject device per the specified guidance and standards. Performance standards IEC 60601-1:2005 + A1:2012 + A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. IEC 60601-1-2:2014 + A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests. IEC TR 60601-4-2:2016 Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems IEC 60601-2-22:2019 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 + A2:2020 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

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	Medical devices - Application of usability engineering to medical devices. IEC 62366-1:2015 Medical devices - Application of usability engineering to medical devices. IEC 62304:2006 + A1:2015 Medical device software - Software life-cycle processes ISO standards ISO 14971:2019 Medical devices - Application of risk management to medical devices ISO 17664-1:2021 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices ISO 17664-2:2021 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process Specified guidance • Software Verification and Validation Testing according to FDA's Guidance (2023),"Content of Premarket Submissions for Device Software Functions | FDA" • Cybersecurity testing according to FDA Guidance document (2023), "Cybersecurity in MedicalDevices: Quality System Considerations and Content of Premarket Submissions | FDA".
8.SUMMARY OF CLINICAL TESTING:	Clinical testing was not considered to be needed for this pre-market notification.
9. CONCLUSIONS	The submitted LightWalker Laser System Family's indications for use and technological

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	characteristics do not raise new types of questions regarding safety and efficacy when compared to predicate. Based on its technical characteristics, design, functional features, performance test data, and its indications for use, the Fotona LightWalker Laser System Family (K242202) is considered to be substantially equivalent to the predicate device (K202985).