October 15, 2019

Fotona d.o.o.
Lina Rupnik
R&D Quality Department
Stegne 7
Ljubljana, 1000 Si

Re: K191554
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: June 7, 2019
Received: June 12, 2019

Dear Lina Rupnik:

This letter corrects our substantially equivalent letter of August 30, 2019.

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,

Purva U. Pandya -S

Purva Pandya
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)*
K191554

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 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 reduction 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.
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Contact Person: Lina Rupnik, R&D Quality Department
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Date: August 21, 2019

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 (K172819)
- Hilthera 4.0 Therapeutical Laser System (K141861)

DEVICE DESCRIPTION

The device is Fotona LightWalker laser system family (same as K172819). 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 0.5 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 intraoral treatments in dentistry, for various surgical and aesthetic applications in dermatology and other surgical areas, and for pain reduction indication stated below.

INTENDED USE

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

Nd:YAG laser (l064 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.

b) Fotona LightWalker Laser System Family and its accessories will also be marketed for the following indications for use, already previously cleared under K172819:

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 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.).

*Note: Permanent hair reduction is defined as the long-term, stable reduction 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 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 (K172819) and the second predicate device Hilthera 4.0 Therapeutical Laser System (K141861). The output characteristics are for the intended use the same as those of the predicate devices. All lasers utilize Class II 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 Table 1 below.

Table 1: Comparison table of the technical specifications for Er:YAG and Nd:YAG laser of Fotona LightWalker Laser System Family, the primary predicate LightWalker Laser System Family (K172819) and the secondary predicate Hilthera 4.0 Therapeutical Laser System (K141861), which is the predicate for the newly submitted indication for use.

	Fotona LightWalker Family		**Jeysis Medical, Inc. Hilthera 4.0**	**Fotona LightWalker Family**		
510(k) number	K172819		K141861	K191554		
Energy source	Er:YAG laser	Nd:YAG laser	Nd:YAG laser	Er:YAG laser	Nd:YAG laser	
Intended use	See Chapter 5.5 b)	See Chapter 5.5 b)	To provide topical heating for the purpose of elevating tissue temperature for temporary relief of muscle & joint pain & stiffness, arthritis pain or muscle spasm; the temporary increase in local blood circulation and/or promoting relaxation of muscle.	See Chapter 5.5 b)	See Chapter 5.5 b)	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.
Laser mode	Pulsed	Pulsed	Pulsed	Pulsed	Pulsed	
Wavelength	2940 nm	1064 nm	1064 nm	2940 nm	1064 nm	
Operating voltage	100-240 VAC		230 VAC	100-240 VAC		
Current frequency	50/60 Hz		50/60 Hz	50/60 Hz		
Power range	Up to 20 W	Up to 15 W	Up to 10 W	Up to 20 W	Up to 15 W	Up to 10 W
Fluence	Up to 48 J/cm^2	Up to 300 J/cm^2	0.15-1.2 J/cm^2	Up to 48 J/cm^2	Up to 300 J/cm^2	0.15-1.2 J/cm^2
Pulse width	50-1000 µs	0.1-25 ms	100-150 µs	50-1000 µs	0.1-25 ms	100-150 µs
Repetition rate	Up to 50 Hz	Up to 100 Hz	10-30 Hz	Up to 50 Hz	Up to 100 Hz	10-30 Hz
Delivery system	Contact and non-contact handpieces connected to the system via an articulated arm	Contact and non-contact handpieces connected to the system via a fiber optic cable	Contact handpieces connected to the system via a fiber optic cable	Contact and non-contact handpieces connected to the system via an articulated arm	Contact and non-contact handpieces connected to the system via a fiber optic cable	
Aiming beam	Laser diode 635 nm/650 nm (red) or 520-532 nm (green); < 1 mW		Laser diode 655 nm (red); 1 mW	Laser diode 635 nm/650 nm (red) or 520-532 nm (green); < 1 mW		
User interface	Touch screen control		Touch screen control	Touch screen control		

STATEMENT OF SUBSTANTIAL EQUIVALENCE

The LightWalker Laser System Family shares the same indication for use, similar design and functional features with the predicate devices, and therefore Fotona believes that LightWalker Laser System Family is substantially equivalent in terms of the indications for use and technology based on technical characteristics to LightWalker Laser System Family (K172819) and to Hilthera 4.0 Therapeutical Laser System (K141861).