K121508

5. 510(k) Summary

DEC 12 2012

Submitter's Name: Fotona d.d.
Stegne 7
1210 Ljubljana, Slovenia
Phone: +386 15009100
Fax: + 386 5009 200

Contact Person: Stojan Trošt, QA&RA Manager
Phone: + 386 1 5009 299
E-mail: stojan.trost@fotona.com

Date: January 11, 2012

Device Name:

Trade name: LightWalker Family

Common name: Er:YAG/Nd:YAG Surgical Laser

Classification name: Instruments, Surgical, Powered, Laser
79-GEX

DEVICE DESCRIPTION

The Fotona LightWalker Laser System Family is based on Er:YAG (2940 nm) and Nd:YAG (1064 nm) laser technology. The laser unit and controls are contained in a single console. Electrical power is supplied to the console by the facility's power source. The unit combines two flashlamp-pumped laser sources in one housing, with optical cavities containing the Er:YAG and Nd:YAG crystals. A red diode aiming beam (650 nm) is combined with both therapeutic laser beams. The combined therapeutic and aiming beams are guided through an articulated arm to an optical manual or scanner hand piece (in the case of the Er:YAG laser), or through an optical fiber delivery system to an optical manual or scanner hand piece (in the case of the Nd:YAG laser). Optionally, the Nd:YAG therapeutic and aiming laser beams can be guided through a fiber having a connector on the proximal end and a bare fiber on the distal end. Fotona's power supply Variable Square Pulse (VSP) Technology, integrated into the laser system, allows control of the laser energy and the laser pulse duration. The user activates laser emission by means of a footswitch.

INTENDED USE

The **LightWalker Er:YAG laser**, and its accessories, are intended for use in dentistry, dermatology and other surgical areas in the following procedures:

In **dentistry**, for:

- Intra-oral soft tissue surgery (incision, excision, ablation, coagulation)
- Leukoplakia
- Pulpotomy as adjunct to root canal retreatment
- Pulp extirpation
- Removal of fibromae
- Removal 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

In **dermatology and other surgical areas,** for:

- Dermatology and Plastic Surgery Indications: Epidermal nevi, actinic cheilitis, skin tags, keratoses, verrucae, 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 mosiac verrucae, matrixectomy
- Ophtalmology Indications: Soft tissue surrounding the eye ;
- Gynecology Indications: Herpes simplex, endometrial adhesion, CIN (Cervical intraepithelial neoplasia), cysts, condiloma;

The **LightWalker Nd:YAG laser,** and its accessories, are intended for use in dentistry, dermatology and other surgical areas in the following procedures:

In **dentistry,** for:

- 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

In **dermatology and other surgical areas,** for:

- 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. 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.
- Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemaongiomae, warts, telengiectasiae, 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.).*

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 devices. The output characteristics are for the intended use the same as those of the predicate devices. All systems are based on VSP (Variable Square Pulse) power supply technology. 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.

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 3 (for the Nd:YAG wavelength) and Table 4 (for the Er:YAG wavelength) below.

Table 3: Comparison table for Nd:YAG laser wavelength

	Fotona Fidelis III (K093162)	Fotona LightWalkerLaser System Family (K101817)	Fotona Dynamis Laser System Family (K101306)	Fotona XP Nd:YAG Laser System Family (K090126) (K113702)	**Fotona LightWalker Laser System Family (new submission)**
Wavelength	1064 nm	1064 nm	1064 nm	1064 nm	**1064 nm**
Laser media	Flashlamp pumped solid state rod	Flashlamp pumped solid state rod	Flash lamp pumped solid state rod	Flashlamp pumped solid state rod	**Flashlamp pumped solid state rod**
Aiming beam	650 nm	650 nm	650 nm	650 nm	**650 nm or optionally 635 nm**
Output mode	Pulsed	Pulsed	Pulsed	Pulsed	**Pulsed**
Pulse energy	up to 10 J	up to 10 J	up to 50 J	up to 20 J	**up to 10 J**
Pulsewidth	0.1-25 ms	0.1-25 ms	0.1 – 50 msec	0.1 – 50 msec	**0.1-25 ms**
Repetition rate	up to 100Hz	up to 100Hz	up to 50 Hz	up to 100Hz	**up to 100Hz**
Power	up to 15 W	up to 15 W	up to 80 W	up to 30 W	**up to 15 W**
Beam delivery	Fiber	Fiber	Fiber	Fiber	**Fiber**
User interface	Push button control	Touch screen control	Push button control	Push button control	**Touch screen control**

Table 4: Comparison table for the Er:YAG wavelength

Er:YAG 2940 nm	Fotona Fidelis III (K093162)	Fotona LightWalker Laser System Family (K101817)	Fotona Dynamis Laser System Family (K101306	**Fotona LightWalker Laser System Family (new submission)**
Wavelength	2940 nm	2940 nm	2940 nm	**2940 nm**
Laser media	Flashlamp pumped solid state rod	Flashlamp pumped solid state rod	Flashlamp pumped solid state rod	**Flashlamp pumped solid state rod**
Aiming beam	650 nm	650 nm	650 nm	**650 nm or optionally 635 nm**

Er:YAG 2940 nm	Fotona Fidelis III (K093162)	Fotona LightWalker Laser System Family (K101817)	Fotona Dynamis Laser System Family (K101306	**Fotona LightWalker Laser System Family (new submission)**
Output mode	Pulsed	Pulsed	Pulsed	**Pulsed**
Pulse energy	25 – 1500 mJ	20 – 1500 mJ	30 – 1500 mJ	**5 – 1500 mJ**
Pulsewidth	50 – 1000 µs	50 – 1000 µs	100 – 1500 µs	**50 – 1000 µs**
Repetition rate	up to 50 Hz	up to 50 Hz	up to 50 Hz	**up to 50 Hz**
Power	up to 20 W	up to 20 W	up to 20 W	**up to 20 W**
Beam Delivery	Articulated arm	Articulated arm	Articulated arm	**Articulated arm**
User interface	Push button control	Touch screen control	Push button control	**Touch screen control**

STATEMENT OF SUBSTANTIAL EQUIVALENCE

The Fotona LightWalaker Er:YAG/Nd:YAG Laser System Family is substantially equivalent to Fotona LightWalker Laser System Family (K101817), Fotona Fidelis III Er:YAG/Nd:YAG Laser System Family (K093162), Fotona Dynamis Er:YAG/Nd:YAG Laser System Family (K101306), Fotona XP Nd:YAG Laser System Family (K090126) and (K113702), Cutera GenesisPlus Laser System (K103626) and PinPointe FootLaser (K093547). The Fotona LightWalker Er:YAG/Nd:YAG Laser System Family is substantially equivalent in terms of indications for use and technology based on technical characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 13, 2013

Fotona D.D.
% Mr. Stojan Trošt
Quality Assurance and Regulatory Affairs Manager
Stegne 7
Ljubljana, Slovenia 1210

Re: K121508
Trade/Device Name: LightWalker 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: PDZ, GEX
Dated: December 07, 2012
Received: December 10, 2012

Dear Mr. Trošt:

This letter corrects our substantially equivalent letter of December 12, 2012.

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,
FOR
Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number K121508

Device Name: **LightWalker Family**

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
- 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;
- Ophthalmology Indications: Soft tissue surrounding the eye;
- Gynecology Indications: Herpes simplex, endometrial adhesion, CIN (Cervical intraepithelial neoplasia), cysts, condiloma;

Neil R Ogden
2012.12.12 08:47:12 -05'00'

(Division Sign-Off)

Division of Surgical Devices

510(k) Number _____

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

Neil R Ogden
2012.12.12 08:47:38 -05'00'

(Division Sign-Off)

Division of Surgical Devices

510(k) Number K121508

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. 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.

  Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemaongiomae, warts, telangiectasia, 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.)*.

Prescription Use: __X__ AND/OR Over-The-Counter Use:_ _ _
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2012.12.12 08:48:11 -05'00'

(Division Sign-Off)

Division of Surgical Devices

510(k) Number __K121508_____