

K101306

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## 5. 510(k) Summary

JUL - 1 2011

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Date: May 5, 2010

Device Trade Name: **Fotona Dynamis Er:YAG/Nd:YAG Laser System Family**

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

Classification name: GEX / Powered Laser Surgical Instrument;  
ORK / Laser Assisted Lipolysis

Legally marketed  
predicate devices: Fotona Dualis SP Nd:YAG/Er:YAG Laser System (K021548)  
Fotona Fidelis III Er:YAG/Nd: YAG Laser System (K093162)  
Fotona XP Nd:YAG Laser System (K090126)  
Fotona XP Plus Nd:YAG Family of Laser Systems (K050293).

### DEVICE DESCRIPTION

The Fotona Dynamis 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.

The Fotona Dynamis Laser System Family is designed to operate in five configurations (models):

- **XS Dynamis:** Single Er:YAG laser system
- **XP Dynamis:** Single Nd:YAG laser system
- **SP Dynamis:** Combined Er:YAG/Nd:YAG laser system
- **XP Spectro:** Single Nd:YAG laser system, with lower average output power of Nd:YAG laser and smaller housing
- **SP Spectro:** Combined Er:YAG/Nd:YAG laser system, with lower average output power of Nd:YAG laser and unchanged specifications of Er:YAG laser, and smaller housing.

## INTENDED USE

The Fotona Dynamis Laser System Family, and its accessories, are intended for use in the following procedures:

### **Dynamis Er:YAG laser (2940 nm wavelength)**

- 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;
- Ophthalmology Indications: Soft tissue surrounding the eye;
- Gynecology Indications: Herpes simplex, endometrial adhesion, CIN (Cervical intraepithelial neoplasia), cysts, condiloma;
- 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 is necessary;
- Podiatry Indications: Warts, plantar verrucae, large mosaic verrucae, matrixectomy;

### **Dynamis Nd:YAG laser (1064 nm wavelength):**

- Surgical incision, excision, vaporization, ablation and coagulation of soft tissue. All soft tissue is included, striated and smooth tissue, muscle, cartilage, meniscus, mucous membrane, lymph vessels and nodes, organs and glands, fibroma removal, frenectomy and frenotomy;
- Laser assisted lipolysis;
- 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;
- Treatment of wrinkles;
- Treatment of mild to moderate inflammatory acne vulgaris;
- Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemaangioma, warts, telangiectasiae, rosacea, venus lake, leg veins and spider veins;
- Endo Venous Laser Therapy of superficial incompetent tributary veins associated with varicose veins and varicosities.

## SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Fotona Dynamis 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 Dynamis 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 Dynamis system family with the previously cleared devices is provided in Table A (for the Nd:YAG wavelength) and Table B (for the Er:YAG wavelength) below.

*Table A: Comparison table for Nd:YAG laser wavelength*

	Fotona XP Plus Nd:YAG Family of Laser Systems (K050293)	Fotona XP Nd:YAG Laser System (K090126)	Fotona Dynamis Laser System Family
<b>Wavelength</b>	1064 nm	1064 nm	1064 nm
<b>Laser media</b>	Flashlamp pumped solid state rod	Flashlamp pumped solid state rod	Flashlamp pumped solid state rod
<b>Aiming beam</b>	650 nm	650 nm	650 nm
<b>Output mode</b>	Pulsed	Pulsed	Pulsed
<b>Pulse energy</b>	up to 120 J	up to 10 J	up to 50 J
<b>Pulsewidth</b>	1 – 200 ms	0.1-50 ms	0.1 – 50 msec
<b>Repetition rate</b>	up to 12 Hz	up to 64 Hz	up to 50 Hz
<b>Power</b>	up to 120 W	up to 30 W	up to 80 W
<b>Beam delivery</b>	Fiber	Fiber	Fiber
<b>User interface</b>	Push button control	Push button control	Push button control

*Table B: Comparison table between the Fotona Dynamis and previously cleared Fotona's and other devices for the Er:YAG laser wavelength*

Er:YAG 2940 nm	Fotona Fidelis III (K093162)	Fotona Dualis SP (K021548)	Fotona Dynamis Family
<b>Wavelength</b>	2940 nm	2940 nm	2940 nm
<b>Laser media</b>	Flashlamp pumped solid state rod	Flashlamp pumped solid state rod	Flashlamp pumped solid state rod

Er:YAG 2940 nm	Fotona Fidelis III (K093162)	Fotona Dualis SP (K021548)	Fotona Dynamis Family
<b>Aiming beam</b>	650 nm	650 nm	650 nm
<b>Output mode</b>	Pulsed	Pulsed	Pulsed
<b>Pulse energy</b>	25 – 1500 mJ	40 – 1000 mJ	30 – 1500 mJ
<b>Pulsewidth</b>	50 – 1000 $\mu$ s	75 - 950 $\mu$ s	100 – 1500 $\mu$ s
<b>Repetition rate</b>	up to 50 Hz	up to 30 Hz	up to 50 Hz
<b>Power</b>	up to 20 W	up to 15 W	up to 20 W
<b>Beam Delivery</b>	Articulated arm	Articulated arm	Articulated arm
<b>User interface</b>	Touch screen and push button control	Push button control	Push button control

### STATEMENT OF SUBSTANTIAL EQUIVALENCE

The Fotona Dynamis Er:YAG/Nd:YAG Laser System Family is substantially equivalent to Fotona Dualis SP Nd:YAG/Er:YAG Laser System (K021548), Fotona Fidelis III Er:YAG/Nd:YAG Laser System (K093162), Fotona XP Nd:YAG Laser System (K090126) and Fotona XP Plus Nd:YAG Family of Laser Systems (K050293). The Fotona Dynamis Er:YAG/Nd:YAG Laser System Family is substantially equivalent in terms of indications for use and technology based on technical characteristics.



Food and Drug Administration  
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% Mr. Stojan Trošt  
Quality Assurance and Regulatory Affairs Manager  
Stegne 7  
1210 Ljubljana, Slovenia

JUL - 1 2011

Re: K101306

Trade/Device Name: Fotona Dynamis Er:YAG/Nd:YAG 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 24, 2011  
Received: June 28, 2011

Dear Mr. Trošt:

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.

Page 2 – Mr. Stojan Trošt

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



*f* Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
And Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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#### 4. Indications for Use Statement

510(k) Number (if known):

Device Name: **Fotona Dynamis Er:YAG/Nd:YAG Laser System Family**

Indications For Use:

**Dynamis Er:YAG laser (2940 nm wavelength)**

- Dermatology and Plastic Surgery Indications: Epidermal nevi, actinic cheilitis, verrucae, skin tags, keratoses and skin resurfacing;
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- Oral/Maxillofacial Indications: Oral and glossal lesions;
- Ophthalmology Indications: Soft tissue surrounding the eye ;
- Gynecology Indications: Herpes simplex, endometrial adhesion, CIN (Cervical intraepithelial neoplasia), cysts, condiloma;
- 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 is necessary;
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- Treatment of mild to moderate inflammatory acne vulgaris;
- Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemaangioma, warts, telangiectasiae, rosacea, venus lake, leg veins and spider veins;
- Endo Venous Laser Therapy of superficial incompetent tributary veins associated with varicose veins and varicosities.

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)

*[Signature]*  
(Division Sign-Off)

Division of Surgical, Orthopedic, and Restorative Devices

510(k) Submission: *Fotona Dynamis Laser System Family*

13/109

510(k) Number K101306