5. 510(k) Summary

JUL 1 1 2014

K132806

1. SUBMITTER'S INFORMATION

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Date Prepared: July 8, 2014

2. DEVICE INFORMATION

Trade Name: **Fotona F-22 Laser Handpiece (F-Runner),**
Fotona FS-01 Laser Handpiece

Common Name: Er:YAG Surgical Laser

Classification Name: Powered laser surgical instrument with microbeam\fractional output

Product Code: ONG, GEX

3. PREDICATE DEVICES

Fotona Dynamis Er:YAG/Nd:YAG Laser System Family (K101306),

JOULE Multi-Platform System (K101916),

Dermablate Effect, ASCLEPION Laser Technologies GmbH (K081541)

4. DEVICE DESCRIPTION

The F-22 Handpiece and FS-01 Handpiece each attach to the Dynamis Er:YAG/Nd:YAG Laser Systems. The Fotona Dynamis Family is based on Er:YAG (2940 nm) and Nd:YAG (1064 nm) laser technology. The F-22 handpiece and FS-01 handpiece are designed to be used with the Er:YAG (2940 nm) laser wavelength only. The laser system console consists of a flashlamp pumped Er:YAG laser source, power supply, water colling unit, electronics, and a footswitch. Electrical power is supplied to the console by the facility's power source. A red diode aiming beam (650 nm) is combined with the therapeutic Er:YAG laser beam. 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). Fotona's power supply and electronics, 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.

4. INTENDED USE

The Fotona F-22 Handpiece is intended for:

- In fractionated mode:

  Dermatological procedures requiring resurfacing of soft tissue with fractionated handpiece;
- In non-fractionated mode:

  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;

The Fotona FS-01 Handpiece is intended for:

- Dermatological procedures requiring resurfacing of soft tissue with fractionated handpiece.

5. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The F-22 Handpiece and FS-01 Handpiece accessories to Fotona Dynamis family have 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. The risk and benefits for the F-22 Handpiece and FS-01 Handpiece accessories to Fotona Dynamis Fotona Dynamis Laser System family are identical to the predicate devices when used for similar clinical applications.

Er:YAG 2940 nm	Sciton JOULE Multi-Platform System Er:YAG (K101916)	Fotona Dynamis Laser System Family (K101306)	Dermablate Effect, ASCLEPION Laser Technologies GmbH (K081541)	Fotona Dynamis 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	630 - 680 nm	650 nm	650 nm	650 nm
Output mode	Pulsed	Pulsed	Pulsed	Pulsed
Pulse energy	20-8000 mJ	30 – 3000 mJ	Up to 1500 mJ	30 – 3000 mJ
Pulsewidth	100 - 500 µs	100 - 1500 µs	400 µs	100 - 300 µs
Repetition rate	Up to 40 Hz	up to 50 Hz	Up to 20 Hz	up to 50 Hz
Power	40W	up to 20 W	Up to 12W	up to 20 W
Beam Delivery	Articulated arm	Articulated arm	Articulated arm	Articulated arm
User interface	LCD Touchscreen	Push button control	LCD Touchscreen	Push button control
Handpieces	ProFractional	R08	Asclepion Dermablate Effect with MicroSpot handpiece	FS-01 F22

Figur1: Comparison table of the technical characteristics for the predicate laser system and for the host laser system for the newly submitted handpieces

6. STATEMENT OF SUBSTANTIAL EQUIVALENCE

The F-22 Handpiece and FS-01 Handpiece are substantially equivalent in terms of indications for use and technology based on technical characteristics to the following predicate devices when used according to its intended use: Fotona Dynamis Er:YAG/Nd:YAG Laser System Family (K101306) and JOULE Multi-Platform System with Profractional handpiece (K101916), Dermablate Effect, ASCLEPION Laser Technologies GmbH (K081541).

7. TESTING

Clinical testing:

A clinical and histological study with the Fotona Dynamis SP laser system (a model from The Fotona Dynamis Er:YAG/Nd:YAG Laser System Family) using FS-01 stamping fractionated handpiece and F22 scanning fractionated handpiece has been performed to demonstrate the benefits of dermatological procedures requiring resurfacing and ablation of soft tissue with the fractionated handpieces.

Non-clinical performance testing

Fotona F-22 Laser Handpiece (F-Runner) and Fotona FS-01 Laser Handpieces are designed, tested and will be manufactured in accordance with both mandatory and voluntary standards including:

- 21 CFR 1040.10 Performance Standards for Light – Emitting Products, Laser products
- 21 CFR 1040.11 Performance Standards for Light – Emitting Products, Specific purpose laser products
- **IEC 60601-1 Ed.3.0: 2005 + Corr 1. 2006 + Corr 2. 2007** - Medical electrical equipment. Part 1: General requirements for basic safety and essential performance
- **IEC 60601-1-2 Ed.3.0: 2007** - Medical electrical equipment. Part 1-2: General requirements for basic safety and essential performance. Collateral standard: Electromagnetic compatibility-Requirements and tests
- **IEC 60601-1-4 Ed. 1.1: 1996 + A1:1999** - Medical electrical equipment. Part 1-4: Collateral standard: Programmable electric medical systems.
- **IEC 60601-1-6 Ed.2.0:2007** - Medical electrical equipment: Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- **IEC 60601-2-22 Ed. 2.0: 1996** - Medical electrical equipment. Part 2: Particular requirements for safety diagnostic and therapeutic laser equipment.
- **IEC 60825-1 Ed. 2.0 /2007** - Safety of laser products. Part 1: Equipment classification and requirements.
- **EN 62304: 2006** - Medical device Software – software life-cycle process
- **ISO 17664:2004** - Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

Laboratory testing was conducted to validate and verify that the proposed handpieces: Fotona F-22 Laser Handpiece (F-Runner) and Fotona FS-01 Laser Handpieces met all design specifications and was substantially equivalent to the predicate devices.

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

July 11, 2014

Fotona d.d.
Stojan Trost
Quality Assurance & Regulatory Affairs Manager
Stegne 7, 1000
Ljubljana, Slovenia

Re: K132806
Trade/Device Name: Fotona F-22 Laser Hand piece (F-Runner),
Fotona FS-01 Laser Handpiece
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: ONG, GEX
Dated: June 12, 2014
Received: June 16, 2014

Dear Stojan Trost:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132806

Device Name
Fotona F-22 (f-runner), Fotona FS-01 laser handpieces

Indications for Use *(Describe)*

The Fotona F-22 Handpiece is intended for:
In fractionated mode:
Dermatological procedures requiring resurfacing of soft tissue with fractionated handpiece;

In non-fractionated mode:
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;

The Fotona FS-01 Handpiece is intended for:
Dermatological procedures requiring resurfacing of soft tissue with fractionated handpiece.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.07.10 16:45:17 -04'00'

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