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

August 18, 2017

Fotona d.o.o.
Stojan Trost
QA&RA Manager
Stegne 7
Ljubljana, 1000 Si

Re: K171227
Trade/Device Name: StarWalker
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: August 16, 2017
Received: July 20, 2017

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" (21 CFR 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,

Jennifer R. Stevenson -S3

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

4 Indications for Use Statement

510(k) Number (if known): K171227

Device Name: **StarWalker Laser System Family**

Indications For Use:

The StarWalker Laser System Family is indicated for:

Specific Indications:

1064 nm wavelength in Q-switched mode:

- Removal of dark (black, blue, brown) tattoo ink
- Treatment of nevus of ota
- Treatment of common nevi
- Removal and lightening of unwanted hair
- Skin resurfacing procedures for the treatment of acne scars and wrinkles

1064 nm wavelength in long pulse mode:

- 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 benign pigmented and benign vascular lesions, such as, but not limited to,
  - port wine stains,
  - hemaongiomae,
  - warts,
  - telangiectasiae,
  - rosacea,
  - venus lake,
  - leg veins and
  - spider veins
- Coagulation and hemostasis of soft tissue
- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris

532 nm wavelength in Q-switched mode (nominal delivered energy of 585 nm and 650 nm with the optional 585 nm and 650 nm dye converter handpieces):

- Red, tan, purple and orange tattoo ink removal
- Sky blue (light) tattoo ink removal
- Green tattoo tattoo ink removal
- Treatment of benign pigmented lesions including, but not limited to:
  - cafe-au-lait birthmarks
  - solar lentigines
  - senile lentigines
  - senile lentigines
  - Becker's nevi
  - freckles
  - common nevi
  - nevus spilus

- Treatment of benign vascular lesion including, but not limited to:
  - port wine birthmarks
  - telangiectasias
  - spider angioma
  - cherry angioma
  - spider nevi
- Seborrheic Keratosis
- Treatment of post-inflammatory hyperpigmentation
- Skin resurfacing procedures for the treatment of acne scars and wrinkles
- Sky blue (light) tattoo ink removal
- Green tattoo tattoo ink removal

532 nm wavelength in long pulse mode:

- The treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size) of the benign vascular lesions (Angiomas, Hemangiomas, Telangiectasia)

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)

5 510(k) Summary

5.1 SUBMITTER'S INFORMATION

Submitter:	Fotona d.o.o. Stegne 7 1000 Ljubljana, Slovenia Phone: +386 1 5009 100 Fax: + 386 1 5009 200
Contact Person:	Stojan Trošt, QA&RA Manager Phone: + 386 1 5009 299 E-mail: stojan.trost@fotona.com
Date:	August 17, 2017

5.2 DEVICE INFORMATION

Device Trade Name:	**StarWalker 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

5.3 PREDICATE DEVICES

- Fotona QX ND:YAG/KTP Laser System Family (K083889)
- Fotona Dualis KTP (532 nm) Laser System and Accessories (K011939)
- Fotona Dynamis Pro Family (K143723)

5.4 DEVICE DESCRIPTION

The Fotona StarWalker Laser System Family is based on the Nd:YAG (1064 nm) and frequency doubled KTP Nd:YAG (532 nm) laser technology. There is one optical cavity containing the Nd:YAG crystal. The frequency doubled KTP Nd:YAG wavelength is achieved by directing the Nd:YAG laser beam through a frequency doubling non-linear crystal. The Nd:YAG laser is activated by means of the use of flashlamps. After the cavity, a red diode aiming beam is reflected onto a coaxial beam path using a beamsplitter assembly. The combined therapeutic and aiming beams are guided by articulated arm to a focusing variable spot handpiece. Optionally, the KTP Nd:YAG beam can be guided to a 585nm dye converter handpiece, or to a 650nm dye laser converter handpiece. The dye handpieces convert the KTP 532 nm wavelength beam into a 585 nm or a 650 nm wavelength, correspondingly. Both lasers are used in non-contact mode. The user activates laser emission by means of a footswitch.

5.5 INTENDED USE

The Fotona StarWalker Laser System Family, and its accessories, are intended for:

1064 nm wavelength in Q-switched mode:

- Removal of dark (black, blue, brown) tattoo ink
- Treatment of nevus of ota
- Treatment of common nevi
- Removal and lightening of unwanted hair
- Skin resurfacing procedures for the treatment of acne scars and wrinkles

1064 nm wavelength in long pulse mode:

- 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 benign pigmented and benign vascular lesions, such as, but not limited to,
  - port wine stains,
  - hemaongiomae,
  - warts,
  - telangiectasiae,
  - rosacea,
  - venus lake,
  - leg veins and
  - spider veins
- Coagulation and hemostasis of soft tissue
- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris

532 nm wavelength in Q-switched mode (nominal delivered energy of 585 nm and 650 nm with the optional 585 nm and 650 nm dye converter handpieces):

- Red, tan, purple and orange tattoo ink removal
- Sky blue (light) tattoo ink removal
- Green tattoo tattoo ink removal
- Treatment of benign pigmented lesions including, but not limited to:
  - cafe-au-lait birthmarks
  - solar lentigines

  - senile lentigines
  - senile lentigines
  - Becker's nevi
  - freckles
  - common nevi
  - nevus spilus
- Treatment of benign vascular lesion including, but not limited to:
  - port wine birthmarks
  - telangiectasias
  - spider angioma
  - cherry angioma
  - spider nevi
- Seborrheic Keratosis
- Treatment of post-inflammatory hyperpigmentation
- Skin resurfacing procedures for the treatment of acne scars and wrinkles

532 nm wavelength in long pulse mode:
- The treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size) of the benign vascular lesions (Angiomas, Hemangiomas, Telangiectasia)

5.6 SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Fotona StarWalker 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 variable pulse duration 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 StarWalker 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 StarWalker Laser System Family with the previously cleared devices is provided in Table A and Table B.

Table A: Comparison table of the technical specifications for Nd:YAG laser of Fotona StarWalker Laser System Family, compared to previously cleared devices

Nd:YAG laser wavelength	**Fotona QX Nd:YAG/KTP LaserSystem Family (K083889)**	**Fotona Dynamis Pro Family (K143723)**	**Fotona StarWalker Laser System Family (this submission)**
Wavelength	1064 nm	1064 nm	1064 nm
Laser media	Flashlamp pumped solid state rod	Flashlamp pumped solid state rod	Flashlamp pumped solid state rod
Aiming beam	635 nm	650 nm	635 nm
Output mode	Pulsed	Pulsed	Pulsed

Nd:YAG laser wavelength	**Fotona QX Nd:YAG/KTP LaserSystem Family (K083889)**	**Fotona Dynamis Pro Family (K143723)**	**Fotona StarWalker Laser System Family (this submission)**
Pulse energy	up to 1.6 J (Q-switched) up to 5 J (long pulsed)	Up to 50 J (long pulsed)	up to 1.6 J (Q-switched) up to 15 J (long pulsed)
Pulsewidth	5 – 20 ns (Q-switched) 0.25 ms (long pulsed)	0.1 – 50 ms (long pulsed)	5 - 20 ns (Q-switched) 0.6 – 50 ms (long pulsed)
Repetition rate	up to 10 Hz	Up to 100 Hz	up to 15 Hz
Beam delivery	Articulated arm	Fiber	Articulated arm
User interface	Push button control	Touch screen	Touch screen

Table B: Comparison table of the technical specifications for Nd:YAG KTP laser of Fotona StarWalker Laser System Family, compared to previously cleared devices

Nd:YAG KTP	**Fotona QX Nd:YAG/KTP Laser System Family (K083889)**	**Fotona Dualis KTP (532 nm) Laser System (K011939)**	**Fotona StarWalker Laser System Family**
Wavelength	532 nm	532 nm	532 nm
Laser media	Flashlamp pumped solid state rod	Flashlamp pumped solid state rod	Flashlamp pumped solid state rod
Aiming beam	635 nm	650 nm	635 nm
Output mode	Pulsed	Pulsed	Pulsed
Pulse energy	up to 0.6 J (Q-switched)	Up to 3.7 J (long pulsed)	Up to 0.6 J (Q-switched) Up to 2 J (long pulsed)
Pulsewidth	5-20 ns (Q-switched)	1 – 150 ms (long pulsed)	5-20 ns (Q switched) 15 - 50 ms (long pulsed)
Repetition rate	up to 10 Hz	up to 10 Hz	up to 10 Hz
Beam delivery	Articulated arm	Fibre - optic	Articulated arm
User interface	Push button control	Push button control	Touch screen

5.7 STATEMENT OF SUBSTANTIAL EQUIVALENCE

The Fotona StarWalker Laser System Family is substantially equivalent to Fotona QX Nd:YAG/KTP Laser System Family (K083889), Fotona Dualis KTP (532 nm) Laser System and Accessories (K011939) and Fotona Dynamis Pro Family (K143723). The Fotona StarWalker Laser System Family is substantially equivalent in terms of indications for use and technology based on technical characteristics.

5.8 TESTING

Clinical testing:

No clinical testing was needed.

Fotona StarWalker laser system family is designed, tested and will be manufactured in accordance with both mandatory and voluntary standards

EN 60601-1:2006 + A1:2013 *
Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance.

EN 60601-1-2:2015♦
Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

EN 60601-2-22:2013 *♦
Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

EN 60601-1-6:2010 + A1:2015 *
Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

EN 62366:2008 + A1:2015 *
Medical devices - Application of usability engineering to medical devices.

EN 60825-1:2014 *
Safety of laser products -- Part 1: Equipment classification and requirements.

EN ISO 14971:2012
Medical devices - Application of risk management to medical devices.

EN 62304:2006 * + A1:2015
Medical device software - Software life-cycle processes.

EN ISO 17664:2004
Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

EN ISO 10993-1:2009
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

* For international compliance see CB Scheme standards
♦ The standard EN 60601-2-22:2013 and EN 60601-1-2:2015 have been published but not harmonized yet. It is however our decision to follow the current state of the art assuming the newer standards assure a higher level of safety.

CB Scheme standards:

IEC 60601-1:2005 + A1:2012
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2:2014
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

IEC 60601-2-22:2007 + A1:2012
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
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

IEC 60825-1:2014
Safety of laser products - Part 1: Equipment classification and requirements.

IEC 62366:2007 + A1:2014
Medical devices - Application of usability engineering to medical devices.

IEC 62304:2006 + A1:2015
Medical device software - Software life-cycle processes.

Laboratory testing has been conducted to validate and verify that the proposed Fotona StarWalker laser system family meets all design specifications and is substantially equivalent to the predicate devices.