November 19, 2020

Fotona d.o.o.
Anja Pucer
Quality Assurance and Regulatory Affairs
Stegne 7
Ljubljana, 1000
Slovenia

Re: K202172
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: July 31, 2020
Received: August 3, 2020

Dear Anja Pucer:

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 Pandya
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)*
K202172

Device Name
StarWalker

Indications for Use *(Describe)*
The StarWalker Laser System Family is indicated 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
-Treatment of melasma
-General dermatology indications: Incision, excision, ablation and vaporization of soft tissue

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
-Removal of epidermal pigmented lesions

532 nm wavelength in long pulse mode:
-Incision, ablation vaporization, coagulation and hemostasis of vascular lesions and soft tissue in various surgical areas. All soft tissue is included, such as skin, cutaneous tissue, subcutaneoous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.
-The treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size) of the benign vascular lesions (Angiomas, Hemangiomas, Telangiectasia)

1064 nm wavelength in PICO mode:
-Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and

purple
-Benign pigmented lesions removal for Fitzpatrick Skin Types I-IV
-Treatment of acne scars in Fitzpatrick Skin Types II-V
-Treatment of wrinkles as well as benign pigmented lesions in Fitzpatrick Skin Types I-IV

532 nm wavelength in PICO mode:
-Tattoo removal in Skin Types I - III
-Treatment of benign pigmented lesions in Fitzpatrick Skin Types I-IV

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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510k Summary

SUBMITTER'S INFORMATION

Submitter:

Fotona d.o.o.
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Phone: +386 1 5009 100

Contact Person:

Anja Pucer, Quality Assurance and Regulatory Affairs
Phone: + 386 1 5009 100
E-mail: anja.pucer@fotona.com

Date:

Novemebr 18, 2020

DEVICE INFORMATION

Device Trade Name:	**StarWalker**
Common name: And In Dermatology	Laser Surgical Instrument For Use In General And Plastic Surgery
Classification name:	GEX-Powered Laser Surgical Instrument 21 CFR 878.4810, Class II
Product Code:	GEX

PREDICATE DEVICES

StarWalker (K171227)

Fotona QX ND:YAG/KTP Laser System Family (K083889)

Fotona Dualis KTP (532 nm) Laser System and Accessories (K011939)

PicoWay Laser System (K191685)

PicoSure Workstation (K173199)

SPECTRA Laser System (K113588)

DEVICE DESCRIPTION SUMMARY

The Fotona StarWalker Laser System Family is based on the previously cleared Fotona StarWalker Laser System Family (K171227).The device 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. The user activates laser emission by means of a footswitch. All handpieces are equipped with sensors for automatic detection of a handpiece type and the spot size.

INTENDED USE/INDICATIONS FOR USE

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
-General dermatology indications: Incision, excision, ablation and vaporization of soft tissue
-Treatment of melasma

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

1064 nm wavelength in PICO mode:
-Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple
-Benign pigmented lesions removal for Fitzpatrick Skin Types I-IV
-Treatment of acne scars in Fitzpatrick Skin Types II-V
-Treatment of wrinkles as well as benign pigmented lesions in Fitzpatrick Skin Types I-IV

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 ink removal
-Treatment of benign pigmented lesions including, but not limited to: cafe-au-lait birthmarks, solar 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

-Removal of epidermal pigmented lesions

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)
-Incision, ablation vaporization, coagulation and hemostasis of vascular lesions and soft tissue in various surgical areas. All soft tissue is included, such as skin, cutaneous tissue, subcutaneoous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

532 nm wavelength in PICO mode:
-Tattoo removal in Skin Types I - III
-Treatment of benign pigmented lesions in Fitzpatrick Skin Types I-IV

INDICATIONS FOR USE COMPARISON

The indications for use from the predicate laser devices that are now included in the Fotona StarWalker Laser System Family do not raise new types of questions regarding safety and effectiveness.

TECHNOLOGICAL COMPARISON

The Fotona StarWalker Laser System Family has either identical or similar applicable technological and design characteristics (design, chemical composition, energy source; wavelength, active medium, cooling system, power supply, beam delivery, controls, housing) as the predicate devices. The output characteristics (pulse width, pulse energy) are the same or similar as those of the predicate devices; the output parameters (fluence, pulsewidth) are the same for the particular intended use as those of the predicate devices.

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)**	**PicoWay Laser System (K191685)**	**SPECTRA Q-Switched Nd:YAG Laser System with Dye Handpieces *(*K113588*)***	**Fotona StarWalker Laser System Family (this submission)**
Wavelength	1064 nm	1064 nm	1064 nm	1064 nm
Laser source	Nd:YAG laser	Nd:YAG laser	Nd:YAG laser	Nd:YAG laser
Output mode	Pulsed	Pulsed	Pulsed	Pulsed
Pulse energy	Up to 1.6 J (Q-switched) Up to 5 J (long pulsed)	Up to 0.4 J	Up to 1.2 J (Q-switched)	Up to 1.6 J (Q-switched) Up to 15 J (long pulsed) Up to 0.8 J (PICO Nd:YAG)
Pulsewidth	5 – 20 ns (Q-switched) 0.25 ms (long pulsed)	450 ps	5 - 10 ns	5 -20 ns (Q-switched) 0.6 - 50 ms (long pulsed) 300 - 400 ps (PICO Nd:YAG)
Repetition rate	Up to 10 Hz	1 - 10 Hz	Up to 10 Hz	0.5 - 15 Hz (Q-switched) 0.5 - 10 Hz (PICO Nd:YAG)

Nd:YAG laser wavelength	**Fotona QX Nd:YAG/KTP LaserSystem Family (K083889)**	**PicoWay Laser System (K191685)**	**SPECTRA Q-Switched Nd:YAG Laser System with Dye Handpieces *(*K113588*)***	**Fotona StarWalker Laser System Family (this submission)**
Beam delivery	Articulated arm with handpieces	Articulated arm with handpieces	Articulated arm with handpieces	Articulated arm with handpieces
User interface	Push button control	Touchscreen with GUI	Touchscreen with GUI	Touchscreen with GUI

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 Dualis KTP (532 nm) Laser System (K011939)**	**SPECTRA Q-Switched Nd:YAG Laser System with Dye Handpieces *(*K113588*)***	**PicoWay Laser System (K191685)**	**PicoSure Workstation (K173199)**	**Fotona StarWalker Laser System Family (this submission)**
Wavelength	532 nm	532 nm	532 nm	532 nm	532 nm
Laser source	Frequency-doubled Nd:YAG laser (KTP)	Frequency-doubled Nd:YAG laser (KTP)	Frequency-doubled Nd:YAG laser (KTP)	Frequency doubled $Nd:YVO_4$	Frequency-doubled Nd:YAG laser (KTP)
Output mode	Pulsed	Pulsed	Pulsed	Pulsed	Pulsed
Pulse energy	Up to 3.7 J (long pulsed)	Up to 0.4 J	Up to 0.2 J	Up to 0.2 J	Up to 2 J (long pulsed) Up to 0.6 J (Q-switched) Up to 0.3 J (PICO KTP)
Pulsewidth	1 – 150 ms (long pulsed)	5 – 10 ns	375 ps	450 - 900 ps	15 - 50 ms (long pulsed) 5 - 20 ns (Q-switched) 300 - 400 ps (PICO KTP)
Repetition rate	Up to 10 Hz	Up to 10 Hz	1 - 10 Hz	1, 2.5, 5, 10 Hz	0.5 - 1 Hz (long pulsed) 0.5 - 10 Hz (Q-switched) 0.5 - 8 Hz (PICO KTP)
Beam delivery	Fibre - optic	Articulated arm with handpieces	Articulated arm with handpieces	Articulated arm with handpieces	Articulated arm with handpieces
User interface	Push button control	Touchscreen with GUI	Touchscreen with GUI	Touchscreen	Touchscreen with GUI

NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY AND CONCLUSIONS

Non-Clinical Summary:

The Fotona StarWalker Laser System Family has been evaluated via verification and validation tests and inspections for conformance to the applicable regulations and safety

standards. The Fotona StarWalker Laser System is designed, tested and will be manufactured in accordance with both, mandatory and voluntary standards.

EN-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 disturbances - 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 17664:2017, Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices

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 disturbances - 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 62366-1:2015 (state-ot-the-art edition), Medical devices - Part 1: Application of usability engineering to medical devices
IEC 62304:2006 + A1:2015, Medical device software - Software life-cycle processes.

ISO standards:
ISO 14971:2007 Medical devices - Application of risk management to medical devices
ISO 17664:2017, Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Clinical Summary:

Not Applicable.

Conclusions:

The Fotona StarWalker Laser System Family shares the applicable indications for use, similar technological characteristics, and similar design and functional features with the predicate devices. These do not raise new types of questions regarding safety and efficacy for the StarWalker Laser System Family when compared to the predicates. Based on its technical characteristics, design, functional features, performance test data, and its indications for use as listed above, the Fotona StarWalker Laser System Family is considered to be substantially equivalent to the predicate devices.