March 27, 2020

Fotona d.o.o.
Marko Berdajs
Quality Assurance and Regulatory Affairs Manager
Stegne 7
Ljubljana, SI-1000 Si

Re: K193656
Trade/Device Name: SkyPulse
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: December 24, 2019
Received: December 30, 2019

Dear Marko Berdajs:

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 postmarketing 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,

Jessica Mavadia-Shukla, Ph.D.
Acting 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)*
K193656

Device Name
SkyPulse Laser Platform

Indications for Use *(Describe)*
2940 nm Er:YAG Laser 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 curettage
-Laser removal of porcelain and ceramic crowns and veneers
-Flap preparation – incision of soft-tissue to prepare a flap and expose the bone
-Cutting bone to prepare a window access to the apex (apices) of the root(s)
-Root-end preparation for retrofill
-Full thickness flap
-Partial thickness flap
-Split thickness flap
-Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
-Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining junctional epithelium
-Excisional and incisional biopsies
-Flap preparation – incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions)
-Frenectomy and frenotomy
-Gingival troughing for crown impressions
-Gingivoplasty
-Implant recovery
-Root canal debridement and cleaning
-Soft tissue crown lengthening
-Laser root canal disinfection after endodontic treatment

2940 nm Er:YAG Laser in dermatology and other surgical areas:
-Dermatology and Plastic Surgery Indications: Skin resurfacing, epidermal nevi, verrucae, skin tags, keratoses, treatment of wrinkles
-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

-Ophthalmology Indications: Soft tissue surrounding the eye
-Gynecology Indications: Herpes simplex, endometrial adhesion, CIN (Cervical intraepithelial neoplasia), cysts, condiloma
-Genitourinary Indications: Lesions of the external genitalia, urethra and anus, penis, scrotum and urethra, vulvar lesions, polyps and familial polyps of the colon

1064 nm Diode Laser in dentistry:
-Excisional and incisional biopsies
-Excision and vaporization of herpes simplex I and II
-Frenectomy and frenotomy
-Gingivectomy
-Gingivoplasty
-Gingival incision and excision
-Hemostasis
-Implant recovery
-Operculectomy
-Pulpotomy and pulpotomy as an adjunct to root canal therapy
-Removal of filling material such as gutta percha or resin as adjunct treatment during root canal therapy
-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)
-Treatment of aphthous ulcers and herpetic lesions

1064 nm Diode Laser in dermatology and other surgical areas:
-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.
-Temporary increase of clear nail in patients with onychomycosis (e.g. dermatophytes Trichophyton rubrum and T mentagrophytes and/or yeasts Candida albicans, etc.)

1064 nm Diode Laser in therapy:
-Temporary relief of muscle and joint pain and stiffness, arthritis pain or muscle spasm, temporary increase in local blood circulation and/or promoting relaxation of muscle.

670 nm Diode Laser in low level laser therapy:
-Temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.

808 nm Diode Laser in dentistry:
Incision, excision, vaporization, ablation and coagulation of oral soft tissues including the following:
-Gingival troughing for crown impression
-Gingivectomy
-Gingivoplasty
-Gingival incision and excision
-Hemostasis and coagulation
-Excisional and incisional biopsies
-Fibroma removal
-Frenectomy and frenotomy
-Oral papillectomies
-Soft tissue crown lengthening
-Treatment of aphthous ulcers
-Treatment of herpetic lesions

Periodontology:
-Laser soft tissue curettage,
-Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
Cosmetic Dentistry:
-Laser-assisted bleaching/whitening of the teeth,
-Light activation for bleaching materials for teeth whitening
Implant recovery

808 nm Diode Laser in therapy:
-Temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.

980 nm Diode Laser in dentistry:
-Gingival troughing
-Crown lengthening
-Gingivoplasty
-Coagulation
-Hemostasis of donor site
-Implant recovery
-Implant uncovery
-Soft tissue curettage
-Sulcular debridement
-Biopsy
-Frenectomy
-Operculectomy
-Exposure of unerupted teeth
-Pulpotomy
-Treatment of aphthous ulcers
-Excision of lesions
-Light activation of bleaching materials for teeth whitening

1470 nm Diode Laser:
-Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue
-Endovascular coagulation and endovenous occlusion of the greatest saphenous vein in patients with superficial vein reflux

1940 nm Diode Laser:
-Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue

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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510(k) Summary K193656

SUBMITTER'S INFORMATION

Submitter:	Fotona d.o.o. Stegne 7 1000 Ljubljana, Slovenia Phone: +386 1 5009 100 Fax: +386 1 5009 200
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Date:	March 26, 2020

DEVICE INFORMATION

Device Trade Name:	**Fotona SkyPulse Laser Platform**
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

PREDICATE DEVICES

- Fotona LightWalker Laser System Family (K191554),
- Biolase WaterLase iPlus Laser System Family (K190319),
- Fotona Dynamis Pro Laser System Family (K182088),
- Fox Q-810, Q-980 and Q-1064 Diode Laser (K073322),
- G.N.S neoLaser neoV Diode Laser Family (K133006),
- Dentsply Sirona SIROLaser Advance+ (K170500),
- Fotona XD Diode Laser System (K083034),
- AMD Picasso Plus (K152939),
- MedX Electronics MedX LPS 200 Portable Laser (Oralase) (K082707),
- Biolase ezlase (K083069),
- Biolase Epic Pro (K163128),
- G.N.S neoLaser neoV980 & neoV1470 Diode Lasers (K152722),
- Sciton Joule Multi-Platorform System (K101916).

DEVICE DESCRIPTION

The Fotona SkyPulse Laser Platform consists of a console, a footswitch and attachable laser modules. The Fotona SkyPulse Laser Platform is a multi-application, multi-technology platform that supports the following modules: i) Flash-lamp pumped solid state laser modules and ii) Diode laser modules. Output parameters and other system features are controlled from the touch-screen control panel on the console, which provides an interface to the system micro-controller through an LCD touch-screen. The console allows simultenous attachment of a solid state laser module and a diode module with up to three selectable diode laser wavelengths.

The following therapeutic laser modules are currently available with the SkyPulse platform: 2940 nm Er:YAG Laser Module, 1064 nm Diode Laser Module, 808 nm Diode Laser Module, 670 nm Diode Laser Module, 980 nm Diode Laser Module, 1470 nm Diode Laser Module and 1940 nm Diode Laser Module. A diode aiming beam is combined with all therapeutic laser beams. The combined therapeutic and aiming beams are guided either through an articulated arm to an optical handpiece (in the case of the Er:YAG laser), or through an optical fiber delivery system to an optical handpiece or to the bare fiber distal end.

INTENDED USE

The Fotona SkyPulse Laser Platform, and its accessories, will be marketed for the following indications:

2940 nm Er:YAG Laser 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 curettage
- Laser removal of porcelain and ceramic crowns and veneers
- Flap preparation – incision of soft-tissue to prepare a flap and expose the bone
- Cutting bone to prepare a window access to the apex (apices) of the root(s)
- Root-end preparation for retrofill
- Full thickness flap
- Partial thickness flap
- Split thickness flap
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the

pocket lining junctional epithelium

- Excisional and incisional biopsies
- Flap preparation – incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions)
- Frenectomy and frenotomy
- Gingival troughing for crown impressions
- Gingivoplasty
- Implant recovery
- Root canal debridement and cleaning
- Soft tissue crown lengthening
- Laser root canal disinfection after endodontic treatment

2940 nm Er:YAG Laser in dermatology and other surgical areas:

- Dermatology and Plastic Surgery Indications: Skin resurfacing, epidermal nevi, verrucae, skin tags, keratoses, treatment of wrinkles.
- 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
- Ophthalmology Indications: Soft tissue surrounding the eye
- Gynecology Indications: Herpes simplex, endometrial adhesion, CIN (Cervical intraepithelial neoplasia), cysts, condiloma
- Genitourinary Indications: Lesions of the external genitalia, urethra and anus, penis, scrotum and urethra, vulvar lesions, polyps and familial polyps of the colon

1064 nm Diode Laser in dentistry:

- Excisional and incisional biopsies
- Excision and vaporization of herpes simplex I and II
- Frenectomy and frenotomy
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis
- Implant recovery
- Operculectomy
- Pulpotomy and pulpotomy as an adjunct to root canal therapy
- Removal of filling material such as gutta percha or resin as adjunct treatment during root canal therapy
- 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)
- Treatment of aphthous ulcers and herpetic lesions

1064 nm Diode Laser in dermatology and other surgical areas:

- 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.
- Temporary increase of clear nail in patients with onychomycosis (e.g. dermatophytes Trichophyton rubrum and T mentagrophytes and/or yeasts Candida albicans, etc.)

1064 nm Diode Laser in therapy:

- Temporary relief of muscle and joint pain and stiffness, arthritis pain or muscle spasm, temporary increase in local blood circulation and/or promoting relaxation of muscle.

670 nm Diode Laser in low level laser therapy:

- Temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.

808 nm Diode Laser in dentistry:

- Incision, excision, vaporization, ablation and coagulation of oral soft tissues including the following:
  - Gingival troughing for crown impression
  - Gingivectomy
  - Gingivoplasty
  - Gingival incision and excision
  - Hemostasis and coagulation
  - Excisional and incisional biopsies
  - Fibroma removal
  - Frenectomy and frenotomy
  - Oral papillectomies
  - Soft tissue crown lengthening
  - Treatment of aphthous ulcers
  - Treatment of herpetic lesions
- Periodontology:
  - Laser soft tissue curettage
  - Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Cosmetic Dentistry:
  - Laser-assisted bleaching/whitening of the teeth
  - Light activation for bleaching materials for teeth whitening
- Implant recovery

808 nm Diode Laser in therapy:

- Temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.

980 nm Diode Laser in dentistry:

- Gingival troughing
- Crown lengthening
- Gingivoplasty
- Coagulation
- Hemostasis of donor site
- Implant recovery
- Implant uncovery
- Soft tissue curettage
- Sulcular debridement
- Biopsy
- Frenectomy
- Operculectomy
- Exposure of unerupted teeth
- Pulpotomy
- Treatment of aphthous ulcers
- Excision of lesions
- Light activation of bleaching materials for teeth whitening

1470 nm Diode Laser:

- Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue
- Endovascular coagulation and endovenous occlusion of the greatest saphenous vein in patients with superficial vein reflux

1940 nm Diode Laser:

- Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Fotona SkyPulse Laser Platform 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 previously cleared Fotona LightWalker Laser System Family (K191554), Biolase WaterLase Laser System Family (K190319), Fotona Dynamis Pro Laser System Family (K182088), Sciton Joule Multi-Platorform System (K101916), Fox Q-810, Q-980 and Q-1064 Diode Laser (K073322), G.N.S neoLaser neoV Diode Laser Family (K133006), Dentsply Sirona SIROLaser Advance+ (K170500), Fotona XD Diode Laser System (K083034), AMD Picasso Plus (K152939), MedX Electronics MedX LPS 200 Portable Laser (Oralase) (K082707), Biolase ezlase (K083069), Biolase Epic Pro (K163128) and G.N.S neoLaser neoV980 & neoV1470 Diode Lasers (K152722). The output characteristics are for the intended use the same as those of the predicate devices. All lasers utilize Class II 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 risks and benefits for the Fotona SkyPulse Laser Platform are identical to the predicate devices when used for similar clinical applications.

A comparison of the technical specifications for the intended use of the Fotona SkyPulse Laser Platform with the previously cleared devices is provided in Tables 1-7.

Table 1: Comparison table of the technical specifications of Fotona SkyPulse Laser Platform with a flash-lamp pumped Er:YAG solid state laser module - with previously cleared devices.

	Sciton Joule Multi-Platorform System (K101916)	**LightWalker Laser System Family** (K191554)	**WaterLase Laser System Family** (K190319)	**Dynamis Pro Laser System Family** (K182088)	**Fotona SkyPulse Laser Platform** (this submission)
Energy source	Solid state Er:YAG	Solid state Er:YAG	Solid state Er,Cr:YSGG	Solid state Er:YAG	Solid state Er:YAG
Wavelength	2940 nm	2940 nm	2780 nm	2940 nm	2940 nm
Aiming beam	Laser diode 630-680 nm	Laser diode 635 nm/650 nm (red) or 520-532 nm (green); < 1 mW	Laser diode 635 nm (red) ; < 1 mW	Laser diode 635 nm/650 nm (red) ; < 1 mW	Laser diode 635 nm/650 nm (red) ; < 1 mW
Power	up to 20 W	Up to 20 W	Up to 10 W	Up to 20 W	Up to 5 W
Energy per pulse	Up to 1500 mJ	Up to 1500 mJ	Up to 600 mJ	Up to 3000 mJ	Up to 400 mJ
Pulse width	150-1500 µs	50-1000 µs	60-700 µs	50-1500 µs	50-1000 µs
Repetition rate	Up to 100 Hz	Up to 100 Hz	Up to 100 Hz	Up to 50 Hz	Up to 40 Hz
Delivery system	Contact and non-contact handpieces connected to the system via articulated arm	Articulated arm	Fiber delivery	Articulated arm	Articulated arm
User interface	Touch screen control	Touch screen control	Touch screen control	Touch screen control	Touch screen control

Table 2: Comparison table of the technical specifications of Fotona SkyPulse Laser Platform with the 1064 nm Diode Laser Module – with previously cleared devices.

	LightWalker Laser System Family (K191554)	**Fox Q-810, Q-980 and Q-1064 Diode Laser** (K073322)	**neoV Diode Laser Family** (K133006)	**Fotona SkyPulse Laser Platform** (this submission)
Energy source	Solid state Nd:YAG	Solid state diode	Solid state diode	Solid state diode
Wavelength	1064 nm	1064 nm	1064 nm	1064 nm
Aiming beam	Laser diode 635 nm/650 nm (red) or 520-532 nm (green); < 1 mW	Laser diode 532 nm (green) ; < 1 mW	Laser diode 532 nm	Laser diode 635 nm/650 nm (red) ; < 1 mW
Power	Up to 15 W	Up to 10 W	Up to 20 W	Up to 32 W
Pulse width	0.1- 25 ms; QCW	0.1 ms – CW	0.1 ms – 30 s; CW	10 ms – 10 s; CW
Repetition rate	Up to 100 Hz	Pulse interval: 0.1 ms – CW	CW or up to 30 Hz	CW or up to 100 Hz
Delivery system	Fiber delivery	Fiber delivery	Fiber delivery	Fiber delivery
User interface	Touch screen control	Touch screen control	Touch screen control	Touch screen control

Table 3: Comparison table of the technical specifications of Fotona SkyPulse Laser Platform with the 670 nm Diode Laser Module – with previously cleared device.

	SIROLaser Advance+ (K170500)	**Fotona SkyPulse Laser Platform** (this submission)
Energy source	Solid state diode	Solid state diode
Wavelength	660 nm	670 nm
Power range	0.1 W	0.1-4 W
Pulse width	10 µs – 0.99 s; CW	10 ms – 10 s; CW
Repetition rate	CW or up to 20 kHz	CW or up to 100 Hz
Delivery system	Fiber delivery	Fiber delivery
User interface	Touch screen control	Touch screen control

Table 4: Comparison table of the technical specifications of Fotona SkyPulse Laser Platform with the 808 nm Diode Laser Module – with previously cleared devices.

	XD Diode Laser System (K083034)	**Picasso Plus** (K152939)	**ezlase** (K083069)	**MedX LPS 200 Portable Laser (Oralase)** (K082707)	**Fotona SkyPulse Laser Platform** (this submission)
Energy source	Solid state diode	Solid state diode	Solid state diode	Solid state diode	Solid state diode
Wavelength	810 ± 10 nm	810 ± 10 nm	810 ± 15 nm	808 nm	808 nm
Power	Up to 7 W	Up to 7 W	Up to 4.5 W	Up to 0.25 W	0.1-33 W
Pulse width	0.025 – 25 ms; CW	20 ms –10 s; CW	0.06 ms – 10 ms; CW	CW	10 ms – 10 s; CW
Repetition rate	CW or 20 Hz – 10 kHz	CW or up to 50 Hz	CW or up to 10 kHz	CW	CW or up to 100 Hz
Delivery	Fiber delivery	Fiber delivery	Fiber delivery	Fiber delivery	Fiber delivery

	XD Diode Laser System (K083034)	**Picasso Plus** (K152939)	**ezlase** (K083069)	**MedX LPS 200 Portable Laser (Oralase)** (K082707)	**Fotona SkyPulse Laser Platform** (this submission)
system					
User interface	Button control	Touch screen control	Touch screen control	Button control	Touch screen control

Table 5: Comparison table of the technical specifications of Fotona SkyPulse Laser Platform with the 980 nm Diode Laser Module – with previously cleared device.

	Epic Pro (K163128)	**Fotona SkyPulse Laser Platform** (this submission)
Energy source	Solid state diode	Solid state diode
Wavelength	980 ± 20 nm	980 nm
Power range	Up to 25 W	Up to 35 W
Pulse width	10 µs – 100 ms; CW	10 ms – 10 s; CW
Repetition rate	CW or up to 20 kHz	CW or up to 100 Hz
Delivery system	Fiber delivery	Fiber delivery
User interface	Touch screen control	Touch screen control

Table 6: Comparison table of the technical specifications of Fotona SkyPulse Laser Platform with the 1470 nm Diode Laser Module – with previously cleared devices.

	Fox Q-810, Q-980 and Q-1064 Diode Laser (K073322)	**neoV980 & neoV1470 Diode Lasers** (K152722)	**Fotona SkyPulse Laser Platform** (this submission)
Energy source	Solid state diode	Solid state diode	Solid state diode
Wavelength	980 nm	1470 nm	1470 nm
Power range	Up to 12 W	Up to 12 W	Up to 22 W
Pulse width	0.1 ms to CW	CW or pulse on: 5-8 s, pulse off: 0.5 s	10 ms – 10 s; CW
Repetition rate	Pulse interval: 0.1 ms – CW	CW or 0.125-0.2 Hz	CW or up to 100 Hz
Delivery system	Fiber delivery	Fiber delivery	Fiber delivery
User interface	Touch screen control	Touch screen control	Touch screen control

Table 7: Comparison table of the technical specifications of Fotona SkyPulse Laser Platform with the 1940 nm Diode Laser Module – with previously cleared device.

	Fox Q-810, Q-980 and Q-1064 Diode Laser (K073322)	**Fotona SkyPulse Laser Platform** (this submission)
Energy source	Solid state diode	Solid state diode
Wavelength	980 nm	1940 nm
Power range	Up to 12 W	Up to 7.5 W
Pulse width	0.1 ms to CW	CW or 10 ms – 10 s
Repetition rate	Pulse interval: 0.1 ms – CW	CW or up to 100 Hz
Delivery system	Fiber delivery	Fiber delivery
User interface	Touch screen control	Touch screen control

TESTING

Clinical testing: No clinical testing was needed.

Fotona SkyPulse Laser Platform 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.
A new version of this standard, EN ISO 17664:2017, has been issued. The 36-month transition period is currently in effect. Transition to new standard version is underway (I-6522).
A new version of this standard, EN ISO 10993-1:2018, has been issued. The 36-month transition period is currently in effect. Transition to new standard version is underway (I-7547).

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 60601-1-9:2007 + A1:2013
Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral standard: Requirements for environmentally conscious design.

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 was conducted to support that the proposed Fotona SkyPulse Laser Platform meets all design specifications and that meets all design specifications and that it is substantially equivalent to the predicate devices.

STATEMENT OF SUBSTANTIAL EQUIVALENCE

The Fotona SkyPulse Laser Platform shares the same indications for use, similar design and functional features with predicate devices, and therefore Fotona believes that Fotona SkyPulse Laser Platform is substantially equivalent to the Fotona LightWalker Laser System Family (K191554), Biolase WaterLase Laser System Family (K190319), Fotona Dynamis Pro Laser System Family (K182088), Sciton Joule Multi-Platorform System (K101916), Fox Q-810, Q-980 and Q-1064 Diode Laser (K073322), G.N.S neoLaser neoV Diode Laser Family (K133006), Dentsply Sirona SIROLaser Advance+ (K170500), Fotona XD Diode Laser System (K083034), AMD Picasso Plus (K152939), MedX Electronics MedX LPS 200 Portable Laser (Oralase) (K082707), Biolase ezlase (K083069), Biolase Epic Pro (K163128) and G.N.S neoLaser neoV980 & neoV1470 Diode Lasers (K152722).

Based on its technical characteristics, performance test data, and its indications for use as listed above, the Fotona SkyPulse Laser Platform is found to be substantially equivalent to the predicate devices.