January 19, 2023

Fotona d.o.o.
Tina Bartolic
Quality Assurance and Regulatory Affaris
Stegne 7
Ljubljana, 1000
Slovenia

Re: K223540
Trade/Device Name: AvalancheLase 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: November 24, 2022
Received: November 25, 2022

Dear Tina Bartolic:

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,

Jianting Wang -S

Jianting Wang
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223540

Device Name
AvalancheLase Family

Indications for Use *(Describe)*
The AvalancheLase Family and its accessories will be marketed for the following indications for use:

Alexandrite laser (755 nm wavelength):
Indications in Dermatology and Aesthetics

• Temporary hair reduction.
• Stable long-term or permanent hair reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. On all skin types (Fitzpatrick I- VI) including tanned skin.
• Treatment of benign pigmented lesions.
• Treatment of wrinkles
• The photocoagulation of benign dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).

Nd:YAG laser (1064 nm wavelength):

The Nd:YAG laser module is intended for incision, ablation, vaporization coagulation and hemostasis of vascular lesions and soft tissue in various dermatological and surgical areas, and for permanent reduction of unwanted hair in Fitzpatrick skin types I - VI.

Indications in Dermatology and Aesthetics:

• 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. Permanent hair reduction is defined as the long-term, stable reduction in the number if hair regrowing when measured at 6, 9 and 12 months after the completion of a treament regime.
• Treatment of wrinkles.
• Treatment of wrinkles with S11 (LX Runner) scanner.
• 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, hemaongiomae, warts, telangiectasiae, rosacea, venus lake, leg veins and spider veins.
• Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
- Matrixectomy
- Radical nail excision
- Periungual and subungual warts
- Plantar warts
- Neuromas
• Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.)

NNd:YAG laser (1064 nm wavelength) 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.

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:

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Tina Bartolic, Quality Assurance and Regulatory Affairs
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E-mail: tina.bartolic@fotona.com

Date:

January 6, 2023

DEVICE INFORMATION

Device Trade Name:	**AvalancheLase Family**
Common name:	Medical Laser System
Classification name:	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology (21 CFR 878.4810; Class II)
Product Code:	GEX

PREDICATE DEVICES

Dynamis Pro Family (K213267)

Family of CoolGlide Aesthetic Lasers (K153671)

GentleMAX Family of Laser Systems (K201111)

GentleLASE Family of Laser Systems (K140732)

DEKA MOTUS AX (K162886)

DEVICE DESCRIPTION SUMMARY

The AvalancheLase Family is based on Nd:YAG (1064 nm) and Alexandrite (755 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 Nd:YAG and Alexandrite crystals. A green diode aiming beam (520 nm) is combined with both therapeutic laser beams. The combined therapeutic and aiming beams are guided through an optical fiber delivery system to an optical manual handpiece or scanner.

The AvalancheLase Family is designed to operate in single wavelength (Nd:YAG or Alexandrite) configurations (models) and dual wavelength (Nd:YAG and Alexandrite) configurations (models).

INTENDED USE/INDICATIONS FOR USE

The AvalancheLase Family and its accessories will be marketed for the following indications for use:

Alexandrite laser (755 nm wavelength):

Indications in Dermatology and Aesthetics

- Temporary hair reduction.
- Stable long-term or permanent hair reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. On all skin types (Fitzpatrick I- VI) including tanned skin.
- Treatment of benign pigmented lesions.
- Treatment of wrinkles.
- The photocoagulation of benign dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).

Nd:YAG laser (1064 nm wavelength):

The Nd:YAG laser module is intended for incision, ablation, vaporization coagulation and hemostasis of vascular lesions and soft tissue in various dermatological and surgical areas, and for permanent reduction of unwanted hair in Fitzpatrick skin types I - VI.

Indications in Dermatology and Aesthetics

- 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. Permanent hair reduction is defined as the long-term, stable reduction in the number if hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.
- Treatment of wrinkles.
- Treatment of wrinkles with S11 (LX Runner) scanner.
- 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, hemaongiomae, warts, telangiectasiae, rosacea, venus lake, leg veins and spider veins;
- Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
  - Matrixectomy
  - Radical nail excision

- Periungual and subungual warts
- Plantar warts
- Neuromas

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

Nd:YAG laser (1064 nm wavelength) 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.

INDICATIONS FOR USE COMPARISON

The indications for use from the predicate devices that are included in the AvalancheLase Family do not raise new types of questions regarding safety and effectiveness. The indications with the Nd:YAG (1064 nm) and Alexandrite (755 nm) laser output are based on previously cleared indications of predicate devices.

TECHNOLOGICAL COMPARISON

A comparison of the technical specifications for the intended use of the AvalancheLase Family with the previously cleared device is provided in Table 1.

Table 1: The comparison of technical capabilities and characteristics between Dynamis Pro Family (K213267), Family of CoolGlide Aesthetic Lasers (K153671), GentleMAX Family of Laser Systems (K201111), GentleLASE Family of Laser Systems (K140732) and DEKA MOTUS AX (K162886) and AvalancheLase Family (this submission) for the Alexandrite and Nd:YAG laser wavelengths

	Fotona Dynamis Pro Family (K213267)	**Cutera Family of CoolGlide Aesthetic Lasers (K153671)**	**Candela GentleMAX Family of Laser Systems (K201111)**	**Candela GentleLASE Family of Laser Systems (K140732)**	**DEKA MOTUS AX (K162886)**	**Fotona AvalancheLase Family (this submission)**	
	Nd:YAG	Alexandrite	Alexandrite	Alexandrite	Alexandrite	Alexandrite	Nd:YAG
Wavelength	1064 nm	755 nm	755 nm	755 nm	755 nm	755 nm	1064 nm
Laser media	Flashlamp solid state Nd:YAG rod	Flashlamp solid state Alexandrite rod	Flashlamp solid state Alexandrite rod	Flashlamp solid state Alexandrite rod	Flashlamp solid state Alexandrite rod	Flashlamp solid state Alexandrite rod	Flashlamp solid state Nd:YAG rod
Aiming beam	650 nm	635 nm	520-550 nm	520-550 nm	532 nm	520 nm	520 nm
Output mode	Pulsed	Pulsed	Pulsed	Pulsed	Pulsed	Pulsed	Pulsed
Fluence	Up to 600 J/cm^2	Up to 100 J/cm^2	Up to 400 J/cm^2	53 J/cm^2	Up to 600 J/cm^2	Up to 500 J/cm^2	Up to 600 J/cm^2
Spotsize	2-20 mm	5 - 18 mm	1.5 -26 mm	6-24 mm	2.5-20 mm	2-30 mm	2-30 mm

Pulse width	0.1 – 50 ms	3 ms	0.25-100 ms	3-300 ms	0.25-300 ms	0.2 – 200 ms	0.1 – 200 ms
Repetition rate	Up to 100 Hz	≤ 2 Hz and single shot	Up to 10 Hz	Max 2 Hz	Up to 10 Hz	Up to 60 Hz*	Up to 80 Hz
Beam Delivery	Fiber	Fiber	Fiber	Fiber	Fiber	Fiber	Fiber
System cooling	Self-contained, water to air heat exchanger	Self-contained, water to air heat exchanger	Self-contained, water to air heat exchanger	Self-contained, water to air heat exchanger	Self-contained, water to air heat exchanger	Self-contained, water to air heat exchanger	Self-contained, water to air heat exchanger
User Interface	LCD Touchscreen	LCD Touchscreen	LCD Touchscreen	LCD Touchscreen	LCD Touchscreen	LCD Touchscreen	LCD Touchscreen

*Not all repetition rate and fluence combinations are possible.

NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY AND CONCLUSIONS

Non-Clinical Summary:

The AvalancheLase Family has been evaluated via verification and validation tests and inspections for conformance to the applicable regulations and safety standards. The AvalancheLase Family is designed, tested and will be manufactured in accordance with both, mandatory and voluntary standards:

AAMI/ANSI ES60601-1:2005(R) 2012 and 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 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 62366-2015
Medical devices - Part 1: Application of usability engineering to medical device

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

ISO standards:

ISO 14971:2019
Medical devices — Application of risk management to medical devices

ISO 17664-1:2021 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

ISO 17664-2:2021 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices

ISO 10993-1:2018 (state-of-the-art edition)*
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Software verification/validation

AvalancheLase Family is a laser device controlled by software. Software verification and validation testing were conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent design flaw could directly result in minor injury to the patient or operator.

Biocompatibility

Biological evaluation according to ISO 10993-1 and the FDA guidance recommendations was performed on handpieces and scanner, which are the only parts that come in direct contact with the patient. Based on nature of body contact and the duration (time) of contact the following endpoints were considered: Physical and/or Chemical Information, Cytotoxicity, Sensitization, Irritation or Intracutaneous Reactivity, Material Mediated Pyrogenicity and Acute Systemic Toxicity.

Clinical Summary:

No premarket clinical investigations for AvalancheLase Family were conduceted since the performance of the device under evaluation is based on well-established laser technology with long history of use for the same intended purpose and it is addtionally sufficently supported by clinical trials assessing performance and safety published in peer reviewed scientific journals.

Conclusions:

The AvalancheLase Family indications for use and technological characteristics do not raise new types of questions regarding safety and efficacy 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 AvalancheLase Family is considered to be as safe, as effective and to perform as well as the predicate devices.