September 8, 2022

Fotona d.o.o.
Marko Berdajs
Quality Assurance and Regulatory Affairs
Stegne 7
Ljubljana, 1000
Slovenia

Re: K213267
Trade/Device Name: Dynamis Pro 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: July 27, 2022
Received: July 27, 2022

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,

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)*
K213267

Device Name
Dynamis Pro Family

Indications for Use *(Describe)*
Er:YAG laser (2940 nm wavelength):

The Dynamis Er:YAG laser is intended for surgical incision/excision, cutting ablation, vaporization and coagulation of soft and hard tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs, and glands.

- Dermatology and Plastic Surgery Indications: Epidermal nevi, actinic cheilitis, verrucae, skin tags, keratoses and soft tissue resurfacing;
- Soft tissue resurfacing with S22 and S22-T scanner;
- ENT Surgery Indications: ENT lesions, cysts, polyps, hyperkeratosis, oral leukoplakia;
- Oral/Maxillofacial Indications: Oral and glossal lesions;
- Uvulopalatoplasty by laser resurfacing
- Ophtalmology Indications: Soft tissue surrounding the eye ;
- Intra-oral soft tissue incision, excision, ablation, coagulation;
- 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;
- 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;
- Podiatry Indications: Warts, plantar verrucae, large mosaic verrucae, matrixectomy;
- 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 and X-Restart Handpieces are intended for:
  - Dermatological procedures requiring resurfacing of soft tissue with fractionated handpiece;

Nd:YAG laser (1064 nm wavelength):
The Dynamis Nd:YAG laser 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.

- Surgical incison, excision, vaporization, ablation and coagulation of soft tissue. All soft tissue is included, striated and smooth tissue, muscle, cartilage, meniscus, mucous membrane, lymph vessels and nodes, organs and glands, fibroma removal, frenectomy and frenotomy;
- Treatment of Aphthous Ulcers;
- Excision and Vaporization of Herpex Simplex I and II;
- Laser assisted uvulopaletoplasty (LAUP);

- Laser assisted lipolysis;
- 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 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.)
- Endo Venous Laser Therapy of superficial incompetent tributary veins associated with varicose veins and varicosities.

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.

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

K213267

SUBMITTER'S INFORMATION

Submitter:

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Contact Person:

Marko Berdajs, Quality Assurance and Regulatory Affairs Manager
Phone: + 386 1 5009 100
E-mail: marko.berdajs@fotona.com

Date:

September 07, 2022

DEVICE INFORMATION

Device Trade Name:	**Dynamis Pro 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

PREDICATE DEVICE

LightWalker Laser System Family (K202985)
Dynamis Pro Family (K182088)

DEVICE DESCRIPTION SUMMARY

The Dynamis Pro Family is based on Er:YAG (2940 nm) and Nd:YAG (1064 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 Er:YAG and Nd:YAG crystals. A red diode aiming beam (650 nm) is combined with both therapeutic laser beams. The combined therapeutic and aiming beams are guided through an articulated arm to an optical manual or scanner handpiece (in the case of the Er:YAG laser), or through an optical fiber delivery system to an optical manual or scanner handpiece (in the case of the Nd:YAG laser).

Optionally, the Nd:YAG therapeutic and aiming laser beams can be guided through a fiber having a connector on the proximal end and a bare fiber on the distal end.

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

INTENDED USE/INDICATIONS FOR USE

The Dynamis Pro Family and its accessories will have the same intended use as predicate device and will be marketed for the following indications for use:

Er:YAG laser (2940 nm wavelength):

The Dynamis Er:YAG laser is intended for surgical incision/excision, cutting ablation, vaporization and coagulation of soft and hard tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs, and glands.

- Dermatology and Plastic Surgery Indications: Epidermal nevi, actinic cheilitis, verrucae, skin tags, keratoses and soft tissue resurfacing;
- Soft tissue resurfacing with S22 and S22-T scanner;
- ENT Surgery Indications: ENT lesions, cysts, polyps, hyperkeratosis, oral leukoplakia;
- Oral/Maxillofacial Indications: Oral and glossal lesions;
- Uvulopalatoplasty by laser resurfacing
- Ophtalmology Indications: Soft tissue surrounding the eye;
- Intra-oral soft tissue incision, excision, ablation, coagulation
- 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;
- 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;
- Podiatry Indications: Warts, plantar verrucae, large mosaic verrucae, matrixectomy;
- 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 and X-Restart Handpieces are intended for:
    - Dermatological procedures requiring resurfacing of soft tissue with fractionated handpiece;

Nd:YAG laser (1064 nm wavelength):

The Dynamis Nd:YAG laser 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.

- Surgical incison, excision, vaporization, ablation and coagulation of soft tissue. All soft tissue is included, striated and smooth tissue, muscle, cartilage, meniscus, mucous membrane, lymph vessels and nodes, organs and glands, fibroma removal, frenectomy and frenotomy;
- Treatment of Aphthous Ulcers;
- Excision and Vaporization of Herpex Simplex I and II;
- Laser assisted uvulopalatoplasty (LAUP);
- Laser assisted lipolysis;
- 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 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.)
- Endo Venous Laser Therapy of superficial incompetent tributary veins associated with varicose veins and varicosities.

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 now included in the Dynamis Pro Family do not raise new types of questions regarding safety and effectiveness. New indications with the Er:YAG (2940 nm) and Nd:YAG (1064 nm) laser output have been introduced, based on previously cleared indications for the substantially equivalent predicate devices.

TECHNOLOGICAL COMPARISON

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

Table 1: The comparison of technical capabilities and characteristics between Dynamis Pro Family (K182088), LightWalker Laser System Family (K202985) and Dynamis Pro Family (this submission) for the Er:YAG and Nd:YAG laser wavelengths

	LightWalker Laser System Family (K202985)		Dynamis Pro Family (K182088)		Dynamis Pro Family (this submission)	
	Er:YAG	Nd:YAG	Er:YAG	Nd:YAG	Er:YAG	Nd:YAG
Wavelength	2940 nm	1064 nm	2940 nm	1064 nm	2940 nm	1064 nm
Laser media	Solid state Er:YAG	Solid state Nd:YAG	Solid state Er:YAG	Solid state Nd:YAG	Solid state Er:YAG	Solid state Nd:YAG
Aiming beam	Laser diode 635 nm/650 nm (red) or 520-532 nm (green); < 1 mW		650 nm (red) ; < 1 mW		650 nm (red) ; < 1 mW	
Output mode	Pulsed	Pulsed	Pulsed	Pulsed	Pulsed	Pulsed
Pulse energy	Up to 1.5 J	Up to 20 J	Up to 3 J	Up to 50 J	Up to 3 J	Up to 50 J
Pulsewidth	0.025 – 1 ms	0.1 - 25 ms	0.1 – 1.5 ms	0.1 – 50 ms	0.1 – 1.5 ms	0.1 – 50 ms
Repetition rate	Up to 50 Hz	Up to 100 Hz	Up to 50 Hz	Up to 100 Hz	Up to 50 Hz	Up to 100 Hz
Power	Up to 20 W	Up to 30 W	Up to 20 W	Up to 80 W	Up to 20 W	Up to 80 W
Beam Delivery	Articulated Arm	Fiber	Articulated Arm	Fiber	Articulated Arm	Fiber
User Interface	LCD Touchscreen		LCD Touchscreen		LCD Touchscreen	

NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY AND CONCLUSIONS

Non-Clinical Summary:

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

ISO standards:

ISO 14971:2007
Medical devices — Application of risk management to medical devices

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

ISO 17664:2017 (state-of-the-art edition)*
Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices

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

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

* With fulfilling the requirements of the latest standard edition, all requirements of previous standard edition are still fulfilled.

Clinical Summary:

N/A

Conclusions:

The Dynamis Pro 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 Dynamis Pro Family is considered to be substantially equivalent to the predicate devices.