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

Re: K182088

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, 2018
Received: August 2, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including
information about labeling regulations, please see Device Advice
(https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn
(http://www.fda.gov/Training/CDRHLearn). 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
(http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone
(1-800-638-2041 or 301-796-7100).

Sincerely,

Neil R.P. Ogden
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

For Enclosure
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;
- Ophthalmology 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 Handpiece is 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 incision, 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 Herpes Simplex I and II;
- Laser assisted uvulopalaetoplasty (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 treatment 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, hemaangiomas, warts, telangiectasias, 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.

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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5 510(k) Summary

SUBMITTER'S INFORMATION

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Date: October 30, 2018

DEVICE INFORMATION

Device Trade Name: Dynamis Pro Family
Common name: Medical Laser System
Classification name: GEX-Powered Laser Surgical Instrument, General and Plastic Surgery
Product Code: GEX

PREDICATE DEVICE

- Fotona Dynamis Pro Family (K143723)

DEVICE DESCRIPTION

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 hand piece (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**

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;
- 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;

**Nd:YAG laser (1064 nm wavelength):**

510(k) Submission: Dynamis Pro Family
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 incision, 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 Herpes Simplex I and II;
- Laser assisted uvulopalaetoplasty (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 treatment 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.

**SUBSTANTIAL EQUIVALENCE DISCUSSION**

The Dynamis Pro 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 device Fotona Dynamis Pro Family (K143723).

The output characteristics for the intended use are the same as those of the predicate device. Both lasers utilize class I aiming beam which pose no hazard to the user. Both systems are microprocessor controlled devices. The microprocessor control regulates normal operation, permits parameter selection and avoids hazard incidence. Both 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 Dynamis Pro Family are identical to the predicate device.
The difference between the subject device and previously cleared device under K143723 is as follows. Additional optical manual and scanner Nd:YAG and Er:YAG hand pieces are added to the list of accessories for the Dynamis Pro Family. Further, the Dynamis Pro Family and its accessories will be marketed for the following additional indications:

Er:YAG laser (2940 nm wavelength):

• Soft tissue resurfacing with S22 and S22-T scanner

Nd:YAG laser (1064 nm wavelength):

• Treatment of wrinkles with S11 scanner

5.1 TESTING

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

EN 60601-1-2006; EN 60601-1:2006/A1:2013
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2007
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
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 60825-1:2014
EN ISO 10993-1:2009
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 14971:2012
Medical devices – application of risk management to medical devices
EN 62304:2006
Medical device Software – software life-cycle process
EN ISO 17664:2004
Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
Medical devices - Application of usability engineering to medical devices
♦ The particular standard EN 60601-2-22:2013 has been published but not harmonized yet, therefore EN 60601-2-22:1996 together with the basic standard EN 60601-1:1990 and its amendments are still effective. It is however our decision to follow the current state of the art assuming the newer standards assure a higher level of safety.
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2007
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential
Laboratory testing has been conducted to validate and verify that the Dynamis Pro Family meets all design specifications and is substantially equivalent to the predicate device.

**STATEMENT OF SUBSTANTIAL EQUIVALENCE**

The Dynamis Pro Family shares similar indications for use, same design and functional features with predicate device, and therefore Fotona believes that its newly submitted Dynamis Pro Family is substantially equivalent to the Fotona Dynamis Pro Family (K143723).