Millennium Dental Technologies, Inc.
Robert H. Gregg
President and Chairman of the Board
10945 South Street, Suite 104-A
Cerritos, California 90703

July 12, 2019

Re: K182930
Trade/Device Name: PerioLase Nd:YAG Pulsed Dental Laser System
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: June 6, 2019
Received: June 7, 2019

Dear Robert H. Gregg:

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,

Neil R.P. Ogden, M.S.
Acting Assistant Director,
Light Based Devices Team
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)*
K182930

Device Name
PerioLase Nd:YAG Pulsed Dental Laser System

Indications for Use *(Describe)*
The PerioLase Nd:YAG Pulsed Dental Laser System is intended for use in laser surgery procedures for ablation, incision, excision, vaporization, and coagulation of soft tissues in specialties such as general and cosmetic dentistry, oral, maxillofacial, and cosmetic surgery, otolaryngology / ENT surgery, arthroscopy, dermatology and plastic surgery, gastroenterology, general surgery, gynecology, neurosurgery, ophthalmology, podiatry, pulmonary surgery, and urology.

Orophayrngeal / Dental Surgery
• Abscess incision and drainage
• Aphthous ulcers treatment
• Biopsies, incisional and excisional
• Excision and ablation of benign lesions and conditions
• Excision and vaporization of herpes simplex I and II
• Exposure of unerupted / partially erupted teeth
• Facilitation of subgingival calculus removal
• Fibroma removal
• Frenectomy
• Frenotomy
• Gingival incision and excision
• Gingival troughing for crown impressions
• Gingivectomy
• Gingivoplasty
• Hemostasis
• Hemostatic assistance
• Implant recovery
• Incision of infection when used with antibiotic therapy
• Laser-assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium)
• Laser-assisted uvulopalatoplasty (LAUP)
• Lesion (tumor) removal
• Leukoplakia
• Modification of the dentin surface, including increasing the mineral and decreasing the organic composition of the dentin surface, reducing bacteria on the dentin surface, improving the shear bond strength of composite resin, reducing the adhesive failure of composite resin, and removing demineralized dentin surfaces
• Operculectomy
• Oral papillectomy
• Periodontal regeneration – true regeneration of the attachment apparatus (new cementum, new periodontal ligament, and new alveolar bone) on a previously diseased root surface when used specifically in the LANAP® Protocol
• Pulpotomy
• Pulpotomy as an adjunct to root canal therapy
• Reduction of denture hyperplasia
• Reduction of gingival hypertrophy
• Removal of filling material such as gutta percha or resin as an adjunct treatment during root canal retreatment
• Removal of post-surgical granulations
• Selective ablation of enamel (first degree) caries removal

• Soft tissue crown lengthening
• 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 level or loss, and tooth mobility
• Tissue retraction for impression
• Vestibuloplasty

General Surgery
Open, laparoscopic, and endoscopic general surgery (ablation, vaporization, incision, excision, 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
• Appendectomy
• Cholecystecomy
• Debridement of decubitus ulcers
• Hemorrhoidectomy
• Hepatectomy
• Herniorrhaphy
• Lymphadenectomy
• Mastectomy
• Pancreatectomy
• Parathyroidectomy
• Partial nephrectomy
• Pelvic adhesiolysis
• Pilonidal cystectomy
• Removal of fibromas
• Removal of lesions
• Removal of polyps
• Removal of tumors
• Resection of lipoma
• Splenectomy
• Thyroidectomy
• Tonsillectomy
• Tumor biopsy

Endonasal Surgery
Endonasal surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
• Adenoidectomy
• Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal tissues
• Tonsillectomy

Dermatology and Plastic Surgery
Dematology and plastic surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
• Debridement of decubitus ulcer
• Hemangiomas
• Lesions of skin and subcutaneous tissue
• Periungual and subungual warts
• Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemangiomae, warts, telangiectasiae, rosacea, venous lake, leg veins, and spider veins
• Plantar warts
• Port wine lesions
• Removal of tattoos
• Spider veins
• Telangiectasia
• Treatment of keloids

• Treatment of mild to moderate inflammatory acne vulgaris
• Treatment of wrinkles
• Venous lakes

Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
• Matrixectomy
• Periungual and subungual warts
• Plantar warts
• Radical nail excision
• Neuromas
The PerioLase® MVP-7™ is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).

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

Submitter:

Millennium Dental Technologies, Inc.
10945 South Street
Suite 306
Cerritos, California 90703
Telephone: (562) 860-2908
Fax: (562) 860-2429
Contact Person: Robert H. Gregg II, DDS, President
Mobile: (562) 577-2454
Date Prepared: July 12, 2019

1. Device Name:

Trade Name:	PerioLase Nd:YAG Pulsed Dental Laser System
Common Name:	Nd:YAG Pulsed Dental Laser
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Regulation:	21 CFR 878.4810
Classification Panel:	General and Plastic Surgery
Device Class:	Class II
Product Code:	GEX

2. Legally Marketed Predicate Devices:

PerioLase, Millennium Dental Technologies, K151763
PinPointe FootLaser, PinPointe USA, K093547
Lightwalker Nd:YAG, Fotona, K121508
SunLase 800 P (PocketPro), Lares Research, K011960
Dentica, Xintec, K971065

3. Device Description:

PerioLase Nd:YAG Pulsed Dental Laser System (same as K010771, K014272, K030290, and K151763)

The laser head consists of a flashlamp-pulsed Nd:YAG rod in an optical resonant cavity. The energy and the width of each laser pulse are determined by the size and shape of the current pulse through the flashlamp. The current pulse through the flashlamp is controlled by the flashlamp switching circuit. This circuit is based on a solid-state switch that sets the current level and pulse width according to the

microprocessor controller. The rate at which the laser pulses are produced, the repetition rate or the pulses/second, is also determined by the microprocessor-controlled switching circuit. The output energy of each laser pulse is measured by the internal energy monitor. This value is compared to the energy setting by the microcontroller and adjustments are made if necessary.

The laser beam emitted from the laser head is coupled into a fiber-optic cable at the fiber port. The presence of the fiber-optic cable is detected by a sensor such that the laser will not fire if the fiber-optic cable is not in place. The laser aperture is at the distal tip of the fiber. The laser head is cooled by circulating water whose excess heat is removed by an air-water heat exchanger.

The operator controls the laser through the touch screen display. The microcontroller handles all of the logic required to set the energy levels, pulse widths, and repetition rates for the laser output, monitors the output pulses to assure proper output energy, monitors all of the interlocks and sensors, and checks for proper operation of the switches, power supplies, and cooling system. Proper operation of the microcontroller is checked by an independent watchdog microprocessor. The system is designed such that no single fault can result in a system failure.

All of the requirements of the laser safety standards of the CDRH as well as of the IEC 60825-1 standard are incorporated, including the remote interlock connector, the laser stop button, the key control, and the safety and manufacturer's labels.

Wavelength	1.064 microns (1064 nm)
Pulse Energy	20 to 300 mJ
Pulse Width	100 µsec to 650 µsec
Repetition Rate	10 to 100 Hz
Average Power	6 Watts maximum
Laser Classification	Class IV

4. Intended Uses:

The PerioLase Nd:YAG Pulsed Dental Laser System is intended for use in laser surgery procedures for ablation, incision, excision, vaporization, and coagulation of soft tissues in specialties such as general and cosmetic dentistry, oral, maxillofacial, and cosmetic surgery, otolaryngology / ENT surgery, arthroscopy, dermatology and plastic surgery, gastroenterology, general surgery, gynecology, neurosurgery, ophthalmology, podiatry, pulmonary surgery, and urology. It is indicated for the following indications for use:

Oropharyngeal / Dental Surgery

- Abscess incision and drainage
- Aphthous ulcers treatment
- Biopsies, incisional and excisional
- Excision and ablation of benign lesions and conditions
- Excision and vaporization of herpes simplex I and II
- Exposure of unerupted / partially erupted teeth
- Facilitation of subgingival calculus removal
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival incision and excision
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Hemostasis
- Hemostatic assistance
- Implant recovery
- Incision of infection when used with antibiotic therapy
- Laser-assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium)
- Laser-assisted uvulopalatoplasty (LAUP)
- Lesion (tumor) removal
- Leukoplakia
- Modification of the dentin surface, including increasing the mineral and decreasing the organic composition of the dentin surface, reducing bacteria on the dentin surface, improving the shear bond strength of composite resin, reducing the adhesive failure of composite resin, and removing demineralized dentin surfaces
- Operculectomy
- Oral Papillectomy
- Periodontal regeneration – true regeneration of the attachment apparatus (new cementum, new periodontal ligament, and new alveolar bone) on a previously diseased root surface when used specifically in the LANAP® Protocol
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Reduction of denture hyperplasia
- Reduction of gingival hypertrophy
- Removal of filling material such as gutta-percha or resin as adjunct treatment during root canal retreatment
- Removal of post-surgical granulations
- Selective ablation of enamel (first degree) caries removal
- Soft tissue crown lengthening
- 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 level or loss, and tooth mobility

- Tissue retraction for impression
- Vestibuloplasty

General Surgery
Open, laparoscopic, and endoscopic general surgery (ablation, vaporization, incision, excision, 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.

- Appendectomy
- Cholecystectomy
- Debridement of decubitus ulcers
- Hemorrhoidectomy
- Hepatectomy
- Herniorrhaphy
- Lymphadenectomy
- Mastectomy
- Pancreatectomy
- Parathyroidectomy
- Partial nephrectomy
- Pelvic adhesiolysis
- Pilonidal cystectomy
- Removal of fibromas
- Removal of lesions
- Removal of polyps
- Removal of tumors
- Resection of lipoma
- Splenectomy
- Thyroidectomy
- Tonsillectomy
- Tumor biopsy

Endonasal Surgery
Endonasal surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:

- Adenoidectomy
- Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal tissues
- Tonsillectomy

Dermatology and Plastic Surgery
Dermatology and plastic surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:

- Debridement of decubitus ulcer
- Hemangiomas
- Lesions of skin and subcutaneous tissue
- Periungual and subungual warts
- Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemangiomae, warts, telangiectasiae, rosacea, venous lake, leg veins, and spider veins

- Plantar warts
- Port wine lesions
- Removal of tattoos
- Spider veins
- Telangiectasia
- Treatment of keloids
- Treatment of mild to moderate inflammatory acne vulgaris
- Treatment of wrinkles
- Venous lakes

Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:

- Matrixectomy
- Periungual and subungual warts
- Plantar warts
- Radical nail excision
- Neuromas

The PerioLase® MVP-7™ is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).

5. Summary of a Comparison of Technological Characteristics:

The comparison table below establishes the basis for the determination of substantial equivalence of the PerioLase Nd:YAG Pulsed Dental Laser System to its named predicate devices.

This submission consolidates soft tissue surgical indications for use of substantially equivalent devices.

Summary of a Comparison of Technological Characteristics

Characteristic	Millennium PerioLase	Millennium PerioLase K151763 3/15/16	PinPointe USA PinPointe FootLaser K093547 10/15/10	Fotona LightWalker Nd:YAG K121508 12/12/12	Lares Research SunLase 800 P (PocketPro) K011960 12/21/01	Xintec Dentica K971065 6/17/97
Product Code Regulation	General & Plastic Surgery and Dermatology GEX, 21 CFR 878.4810	General & Plastic Surgery and Dermatology GEX, 21 CFR 878-4810	General & Plastic Surgery and Dermatology GEX, 21 CFR 878.4810	General & Plastic Surgery and Dermatology GEX, 21 CFR 878.4810	General & Plastic Surgery and Dermatology GEX, 21 CFR 878.4810	General & Plastic Surgery and Dermatology GEX, 21 CFR 878.4810
Regulation Medical Specialty	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery
510(k) Review Panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery
Device Class	II	II	II	II	II	II
Laser Class	IV (4)	IV (4)	IV (4)	IV (4)	IV (4)	IV (4)
Intended Use	Intended for use in laser surgery procedures for ablating, incising, excising, vaporizing, and coagulating soft tissues in specialties such as general and cosmetic dentistry, including tooth whitening, modification of dentin surface, temporary relief of pain, oral, maxillofacial, and cosmetic surgery, otolaryngology / ENT surgery, arthroscopy, dermatology and plastic surgery, gastroenterology, general surgery, gynecology, neurosurgery, ophthalmology, podiatry, pulmonary surgery, and urology	Intended for ablating, incising, excising, vaporization and coagulation of soft tissues using a contact fiber-optic delivery system. The device will be used in the following areas: general and cosmetic dentistry, otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology & plastic surgery, neurosurgery, gynecology, urology, ophthalmology, & pulmonary general surgery	Intended for use in general and cosmetic dentistry, otolaryngology/ENT surgery, dermatology and plastic surgery, oral maxillofacial and cosmetic surgery, and podiatry	Intended for use in dentistry, dermatology, general surgery, and podiatry	Indicated for ablating, incising, excising, vaporization, and coagulation of soft tissues. The device will be used in general and cosmetic dentistry, otolaryngology, dermatology, and plastic surgery.	Indicated for incision/excision, ablation, and coagulation (homeostasis) of soft tissue and cartilage. Specific surgical specialties include dentistry, oral surgery, ear nose & throat (ENT), head and neck surgery, thoracic surgery, neurology (homeostasis only), dermatology, plastic surgery, general surgery
Wavelength	1064 nm	1064 nm	1064 nm	1064 nm	1064 nm	1064 nm
Aiming Beam	630-680 nm (≤ 5.0 mW)	660 nm (1 mW)	630-680 nm (< 2.5 mW)	650 nm (≤ 1 mW)	633 nm (1 mW)	632.8 nm (5 mW)
Power Watts	6W	6W	6W, 30W, 100W	8 W	8 W	15 W
Pulse Duration (µsec)	100, 150, 250, 350, 450, 550, 650	100, 150, 250, 350, 450, 550, 650	100-700 (6W), 350-3000 (30W), 350-3000 (100W)	100, 180, 650	110, 280	100, 160, 300, 500, 700
Energy per pulse (mJ)	20-300	20-300	20-200 (6W), 20-1000 (30W), 20-3500 (100W)	≤ 10,000 mJ	30 to 400	100 to 200
Output Mode	Pulsed, multi-mode	Pulsed, multi-mode	Pulsed, multi-mode	Pulsed	Pulsed	Pulsed
Repetition Rate	10-100 Hz	10-100 Hz	5-100 Hz	10-100 Hz	10-50 Hz	10-30 Hz

Characteristic	Millennium PerioLase	Millennium PerioLase K151763 3/15/16	PinPointe USA PinPointe FootLaser K093547 10/15/10	Fotona LightWalker Nd:YAG K121508 12/12/12	Lares Research SunLase 800 P (PocketPro) K011960 12/21/01	Xintec Dentica K971065 6/17/97
Laser Medium	Flashlamp-pumped, solid-state laser rod	Flashlamp-pumped, solid state laser rod	Flashlamp-pumped, solid state laser rod	Flashlamp-pumped solid state rod	Flashlamp-pumped solid state rod	Flashlamp-pumped solid state rod
User Interface	Touch screen control panel	Touch screen control panel	Push-button control panel	Touch screen control	Touch screen control	Touch screen control
Laser Activation	Footswitch	Footswitch	Footswitch	Footswitch	Footswitch	Footswitch
Beam Delivery	Fiber 300, 360, 400 µm	Fiber 200, 320, 400, 600 µm	Fiber 200 to 1000 µm	Fiber 320 µm	Fiber 200, 320 µm	Fiber 300, 320, 400, 600 µm
Soft Tissue Cutting Method	Contact	Contact	Contact	Contact	Contact	Contact
Electrical Requirements	100-240 VAC, 50/60 Hz, 8 A/4 A	120 VAC, 10 A or 220 VAC, 5 A, 50/60 Hz	90-130 VAC, 50/60 Hz 200-240 VAC, 50/60 Hz	230 VAC, 10 A, 50/60 Hz	120 VAC, 10 A, 50/60 Hz 220 VAC, 5 A, 50/60 Hz	120 VAC, 20 A, 60 Hz
System Dimensions	11” W x 19” D x 25” H	11” W x 16.5” D x 28” H	13” W x 14” D x 32” H	11.4” W x 21.6” D x 32.2” H	10” W x 18” D x 31” H	10” W x 22” D x 36” H
System Weight	45 lbs	45 lbs	38 lbs	130 lbs	110 lbs	150 lbs
Cooling	Air-cooled (internal water loop)	Air-cooled (internal water loop)	Air-cooled (internal water loop)	Air-cooled (internal water loop)	Air-cooled (internal water loop)	Air-cooled (internal water loop)

Summary of a Comparison of Indications for Use

Characteristic	Millennium PerioLase	Millennium PerioLase K151763 3/15/16	PinPointe USA PinPointe FootLaser K093547 10/15/10	Fotona LightWalker Nd:YAG K121508 12/12/12	Lares Research SunLase 800 P (PocketPro) K011960 12/21/01	Xintec Dentica K971065 6/17/97
Indications for Use Statement	Intended Uses of the Device: The PerioLase Nd:YAG Pulsed Dental Laser System is intended for use in laser surgery procedures for ablation, incision, excision, vaporization, and coagulation of soft tissues in specialties such as general and cosmetic dentistry, oral, maxillofacial, and cosmetic surgery, otolaryngology / ENT surgery, arthroscopy, dermatology and plastic surgery, gastroenterology, general surgery, gynecology, neurosurgery, ophthalmology, podiatry, pulmonary surgery, and urology.	Intended Uses of the Device: The PerioLase Nd:YAG Pulsed Dental Laser System is to provide the ability to perform intraoral soft tissue dental, general, oral maxillofacial, and cosmetic surgery. The PerioLase is intended for ablating, incising, excising, vaporization and coagulation of soft tissues using a contact fiber-optic delivery system. The device will be used in the following areas: general and cosmetic dentistry, otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology & plastic surgery, neurosurgery, gynecology, urology, ophthalmology, and pulmonary general surgery.	The PinPointe™ FootLaser™ and the delivery accessories that are used with them are intended for use in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in the medical specialties of general and cosmetic dentistry, otolaryngology / ENT surgery, and dermatology & plastic surgery including intraoral soft tissue dental surgery, oral maxillofacial and cosmetic surgery, general surgery, E.N.T. surgery, podiatry, and dermatology and plastic surgery.	Intended for use in dentistry, dermatology, and other surgical areas.	Performs intraoral soft tissue dental, general, oral maxillo-facial and cosmetic surgery. Intended for use in general and cosmetic dentistry, otolaryngology, dermatology, and plastic surgery.	Indicated for incision/excision, ablation, and coagulation (homeostasis) of soft tissue and cartilage. Soft tissue which may be encountered in surgical procedure includes skin, subcutaneous tissue, striated and smooth muscle, cartilage, mucous membrane, lymph vessels and nodes, organs and glands. Specific surgical specialties include dentistry, oral surgery, ear nose and throat (ENT), head and neck surgery, thoracic surgery, neurology (homeostasis only), dermatology, plastic surgery, general surgery.
Oropharyngeal / Dental Surgery Indications for Use	Oropharyngeal / Dental Surgery • Abscess incision and drainage • Aphthous ulcers treatment • Biopsies, incisional and excisional • Excision and ablation of benign lesions and conditions • Excision and vaporization of herpes simplex I and II • Exposure of unerupted / partially erupted teeth • Facilitation of subgingival calculus removal • Fibroma removal • Frenectomy • Frenotomy • Gingival incision and excision • Gingival troughing for crown impressions • Gingivectomy • Gingivoplasty • Hemostasis • Hemostatic assistance • Implant recovery • Incision of infection when used with antibiotic therapy • Laser-assisted new attachment procedure (cementum-mediated periodontal ligament new-	Intended use: The following are the oropharyngeal indications for use for which the device will be marketed: • Abscess Incision and Drainage • Aphthous ulcers treatment • Biopsies excision and incision • Crown lengthening • Hemostatic assistance • Fibroma removal • Frenectomy • Frenotomy • Gingival Incision and Excision • Gingivectomy • Gingivoplasty • Operculectomy • Oral Papillectomy • Tissue retraction for impression • Vestibuloplasty • Selective ablation of enamel (first degree) caries • Exposure of unerupted / partially erupted teeth • Implant recovery • Lesion (tumor) removal • Leukoplakia • Pulpotomy • Pulpotomy as adjunct to root	Oropharyngeal / Dental Surgery Indicated for: • Abscess incision and drainage • Aphthous ulcers treatment • Biopsies, excisional and incisional • Crown lengthening • Exposure of unerupted / partially erupted teeth • Fibroma removal • Frenectomy • Frenotomy • Gingival incision and excision • Gingivectomy • Gingivoplasty • Hemostasis • Implant recovery • Lesion (tumor) removal • Leukoplakia • Operculectomy • Oral papillectomy • Pulpotomy • Pulpotomy as adjunct to root canal therapy • Removal of filling material such as gutta-percha or resin as adjunct treatment during root canal re-treatment • Selective ablation of enamel (first degree) caries removal	Nd:YAG laser (1064 nm wavelength) in dentistry: • Excisional and incisional biopsies • Excision and vaporization of herpes simplex I and II • Exposure of unerupted teeth • Fibroma removal • Frenectomy and frenotomy • Gingival troughing for crown impressions • Gingivectomy • Gingivoplasty • Gingival incision and excision • Hemostasis • Implant recovery • Incision and drainage of abscess • Laser assisted uvulopalatoplasty (LAUP) • Operculectomy • Oral papillectomies • Pulpotomy and pulpotomy as an adjunct to root canal therapy • Reduction of denture hyperplasia • Reduction of gingival hypertrophy • Removal of filling material	The SunLase 800P laser device is to provide the ability to perform intraoral soft tissue dental, general, oral maxillofacial, and cosmetic surgery. The device is indicated for ablating, incising, excising, vaporization, and coagulation of soft tissues using a contact, fiber-optic delivery system. The device will be used in the following area: general and cosmetic dentistry, otolaryngology, dermatology, and plastic surgery. The following are the oropharyngeal indications for use for which the device will be marketed: • Excisional and incisional biopsies • Excision and vaporization of herpes simplex I and II • Exposure of unerupted teeth • Fibroma removal • Frenectomy and frenotomy • Gingival troughing for crown impressions • Gingivectomy • Gingivoplasty • Gingival incision and excision • Hemostasis • Implant recovery	Dentistry: • Gingivectomy • Gingivoplasty • Incision and excision • Laser curettage Oral Surgery: • Crown lengthening • Excision and ablation of benign and malignant lesions and conditions • Frenectomy • Hemostasis • Incisional and excisional aphthous ulcers • Incisional and excisional biopsy • Incision of infection when used with antibiotic therapy • Operculectomy

Characteristic	Millennium PerioLase	Millennium PerioLase K151763 3/15/16	PinPointe USA PinPointe FootLaser K093547 10/15/10	Fotona LightWalker Nd:YAG K121508 12/12/12	Lares Research SunLase 800 P (PocketPro) K011960 12/21/01	Xintec Dentica K971065 6/17/97
	attachment to the root surface in the absence of long junctional epithelium) • Laser-assisted uvulopalatoplasty (LAUP) • Lesion (tumor) removal • Leukoplakia • Modification of the dentin surface, including increasing the mineral and decreasing the organic composition of the dentin surface, reducing bacteria on the dentin surface, improving the shear bond strength of composite resin, reducing the adhesive failure of composite resin, and removing demineralized dentin surfaces • Operculectomy • Oral Papillectomy • Periodontal regeneration – true regeneration of the attachment apparatus (new cementum, new periodontal ligament, and new alveolar bone) on a previously diseased root surface when used specifically in the LANAP® Protocol • Pulpotomy • Pulpotomy as an adjunct to root canal therapy • Reduction of denture hyperplasia • Reduction of gingival hypertrophy • Removal of filling material such as gutta-percha or resin as an adjunct treatment during root canal retreatment • Removal of post-surgical granulations • Selective ablation of enamel (first degree) caries removal • Soft tissue crown lengthening • 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	canal therapy • Removal of filling material such as gutta-percha or resin as adjunct treatment during root canal retreatment • Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment level and tooth mobility • Laser-assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium) • Periodontal regeneration – true regeneration of the attachment apparatus (new cementum, new periodontal ligament, and new alveolar bone) on a previously diseased root surface when used specifically in the LANAP® Protocol	• Sulcular debridement (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 • Tissue retraction for impressions • Vestibuloplasty	such as gutta-percha or resin as adjunct treatment during root canal therapy • Removal of post-surgical granulations • Soft tissue crown lengthening • 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) • Tissue retraction for impression • Treatment of aphthous ulcers • Vestibuloplasty	• Incision and drainage of abscess • Laser assisted uvulopalatoplasty (LAUP) – This laser is effective for cutting, ablating, coagulating, and removing oropharyngeal soft tissue that has been diagnosed as anatomically abnormal or naturally occurring hypertrophic which has been identified and confirmed as being associated with chronic palatal snoring. • Leukoplakia • Operculectomy • Oral papillectomies • Pulpotomy and pulpotomy as an adjunct to root canal therapy • Reduction of denture hyperplasia • Reduction of gingival hypertrophy • Removal of filling material such as gutta-percha or resin as adjunct treatment during root canal therapy • Removal of post-surgical granulations • Selective ablation of enamel (first degree caries removal) • Soft tissue crown lengthening • 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) • Tissue retraction for impression • Treatment of aphthous ulcers • Vestibuloplasty	

Characteristic	Millennium PerioLase	Millennium PerioLase K151763 3/15/16	PinPointe USA PinPointe FootLaser K093547 10/15/10	Fotona LightWalker Nd:YAG K121508 12/12/12	Lares Research SunLase 800 P (PocketPro) K011960 12/21/01	Xintec Dentica K971065 6/17/97
	level or loss, and tooth mobility • Tissue retraction for impression • Vestibuloplasty					
General Surgery Indications for Use	General Surgery Open, laparoscopic, and endoscopic general surgery (ablation, vaporization, incision, excision, 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 • Appendectomy • Cholecystectomy • Debridement of decubitus ulcer • Hemorrhoidectomy • Hepatectomy • Herniorrhaphy • Lymphadenectomy • Mastectomy • Pancreatectomy • Parathyroidectomy • Partial nephrectomy • Pelvic adhesiolysis • Pilonidal cystectomy • Removal of fibromas • Removal of lesions • Removal of polyps • Removal of tumors • Resection of lipoma • Splenectomy • Thyroidectomy • Tonsillectomy • Tumor biopsy		General Surgery Indicated for: Open, laparoscopic, and endoscopic general surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including: • Cholecystectomy • Lymphadenectomy • Mastectomy • Partial nephrectomy • Hepatectomy • Pilonidal cystectomy • Pancreatectomy • Resection of lipoma • Splenectomy • Pelvic adhesiolysis • Hemorrhoidectomy • Removal of lesions • Thyroidectomy • Removal of polyps • Parathyroidectomy • Removal of tumors • Herniorrhaphy • Tumor biopsy • Tonsillectomy • Debridement of decubitus ulcers • Appendectomy	General surgery indications: surgical incision, excision, vaporization, 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.		• General Surgery • Head and Neck Surgery • Thoracic Surgery
Endonasal Surgery Indications for Use	Endonasal Surgery Endonasal surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including: • Adenoidectomy • Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal tissues • Tonsillectomy		Endonasal Surgery Endonasal surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including: • Lesions or tumors of the oral, nasal, glossal, pharyngeal & laryngeal tissues • Tonsillectomy • Adenoidectomy			• Ear Nose & Throat (ENT)
Dermatology and Plastic Surgery Indications for Use	Dermatology and Plastic Surgery Dermatology and plastic surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:		Dermatology and Plastic Surgery Dermatology and plastic surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:	Nd:YAG laser (1064 nm wavelength) in dermatology and other surgical areas: • Removal of unwanted hair, for stable long term or		• Dermatology • Plastic Surgery

Characteristic	Millennium PerioLase	Millennium PerioLase K151763 3/15/16	PinPointe USA PinPointe FootLaser K093547 10/15/10	Fotona LightWalker Nd:YAG K121508 12/12/12	Lares Research SunLase 800 P (PocketPro) K011960 12/21/01	Xintec Dentica K971065 6/17/97
	• Debridement of decubitus ulcer • Hemangiomas • Lesions of skin and subcutaneous tissue • Periungual and subungual warts • Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemangiomae, warts, telangiectasiae, rosacea, venous lake, leg veins, and spider veins • Plantar warts • Port wine lesions • Removal of tattoos • Spider veins • Telangiectasia • Treatment of keloids • Treatment of mild to moderate inflammatory acne vulgaris • Treatment of wrinkles • Venous lakes		• Lesions of skin and subcutaneous tissue • Telangiectasia • Port wine lesions • Spider veins • Hemangiomas • Plantar warts • Periungual and subungual warts • Removal of tattoos • Debridement of decubitus ulcer • Treatment of keloids	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 of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. • Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemaongiomae, warts, telangiectasiae, rosacea, venous lake, leg veins and spider veins • Treatment of wrinkles • Treatment of mild to moderate inflammatory acne vulgaris		
Podiatry	Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including: • Matrixectomy • Periungual and subungual warts • Plantar warts • Radical nail excision • Neuromas The PerioLase® MVP-7™ is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T. mentagrophytes,* and/or yeasts *Candida albicans,* etc.).		Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including: • Matrixectomy • Periungual and subungual warts • Plantar warts • Radical nail excision • Neuromas The PinPointe™ FootLaser™ is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T. mentagrophytes,* and/or yeasts *Candida albicans,* etc.).	Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including: • Matrixectomy • Periungual and subungual warts • Plantar warts • Radical nail excision • Neuromas The Fotona LightWalker Laser System Family is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T. mentagrophytes,* and/or yeasts *Candida albicans,* etc.).		

The PerioLase MVP-7 has the following technological similarities to the named predicate devices;

- Same product code and regulation: GEX, 21 CFR 878.4810
- Equivalent user interface
- Same laser activation method: footswitch
- Same output mode: pulsed
- Equivalent delivery system: optical fiber
- Equivalent patient contacting component: fiber tip
- Same soft tissue cutting methods: tissue contact
- Equivalent mechanism of action: light converted to heat

The PerioLase MVP-7 is a free-running Nd:YAG solid-state laser based on the same technology as the predicate Nd:YAG lasers. The specific user interfaces and displays (control panel) differ among the devices, but these differences are considered minor since the panels control the same types of operational parameters on their respective devices. The PerioLase Nd:YAG Pulsed Dental Laser System includes a built-in power meter for additional functionality which enables the user to confirm the power being emitted at the optical fiber tip with the power being displayed on the touch screen. Hence, the intended use and indications for use on soft tissue are the same as or equivalent to the predicate devices. This consolidation of clinical applications presents no new issues.

6. Nonclinical Performance Data:

The PerioLase Nd:YAG Pulsed Dental Laser System has been evaluated via verification and validation tests and inspections for conformance to applicable regulations and safety standards. Each PerioLase is tested for electrical safety and output characteristics to ensure it meets the design criteria for essential performance, its safety features and functions operate correctly, and it satisfies the performance requirements specified in 21 CFR 1010 and 21 CFR 1040. Representative data is presented in the Performance section and Appendix C of the previous PerioLase submission K151763.

7. Clinical and Laboratory Performance Data:

Human and animal studies demonstrate the ability of a pulsed neodymium dental laser to remove subgingival calculus and modify the surface of dentin. The relevant clinical and laboratory reports are provided in Appendix B of this submission. Based on these reports, the following new indications for use are added:

- Facilitation of subgingival calculus removal
- Modification of the dentin surface, including increasing the mineral and decreasing the organic composition of the dentin surface, reducing bacteria on the dentin surface, improving the shear bond strength of composite resin, reducing the adhesive failure of composite resin, and removing demineralized dentin surfaces

8. Conclusions:

The PerioLase Nd:YAG Pulsed Dental Laser System is substantially equivalent to the predicate devices in functional and performance characteristics, and for the intended uses in the stated medical specialties. The PerioLase is designed to comply with applicable federal and international safety and performance standards.