May 8, 2025

Wuhan Pioon Technology Co., Ltd.
Tracy Liu
Regulatory Affairs
12th Fl, Bldg 1, Innovative Unit, R&D Center Project,Marine
World Shipyard Pk,No. 16 Fozuling 3rd Rd, East Lake High
Wuhan, Hubei 430205
CHINA

Re: K243764
Trade/Device Name: Medical Diode Laser (UTU3-F7B,UTU3-F7W,UTU3-G7B,UTU3-G7W,UTU-G20B,UTU-G20W)
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: NVK, GEX, ILY
Dated: December 6, 2024
Received: December 6, 2024

Dear Tracy Liu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243764

Device Name

Medical Diode Laser (UTU3-F7B,UTU3-F7W,UTU3-G7B,UTU3-G7W,UTU-G20B,UTU-G20W)

Indications for Use *(Describe)*

The UTU series Medical Diode Laser are intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and inter-dental and epithelial lining of free gingiva and are indicated for: frenectomy; frenotomy; biopsy; operculectomy; implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of donor site; removal of granulation tissue; laser assisted flap surgery; debridement of diseased epithelial lining; incisions and draining of abscesses; tissue retraction for impressions; papillectomy; vestibuloplasty; excision of lesions; exposure of unerupted/partially erupted teeth; removal of hyperplastic tissues; treatment of aphthous ulcers; leukoplakia; laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index,gingival bleeding index, probe depth, attachment loss and tooth inability); pulpotomy; pulpotomy as adjunct to root canal therapy; fibroma removal; gingival incision and excision; treatment of canker sores; herpetic ulcers of the oral mucosa; laser soft tissue curettage; reduction of gingival hypertrophy.

Whitening: The UTU series Medical Diode Laser are indicated for light activation for bleaching materials for teeth whitening and for laser-assisted whitening/bleaching of teeth.

Low Level Laser Therapy: The UTU series Medical Diode Laser are intended to emit energy in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.

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

In accordance with the content and format regulatory requirements of 21 CFR Part 807.92,the 510(k) Summary for the Medical Diode Laser is provided below.

The assigned 510(k) Number: **K243764**

1. Submitter

Submitter's Name: Wuhan Pioon Technology Co.,Ltd.
Address:12th Floor, Building 1, Innovative Unit, R&D Center Project, Marine World Shipyard Park, No. 16 Fozuling 3rd Road, East Lake High-tech Development Zone, 430205, Wuhan, Hubei,China
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Official Correspondent: Tracy Liu, Wuhan Pioon Technology Co.,Ltd.
Phone: +86 15012997429
Email: tracy@pioon.com

Date Prepared: April 8, 2025

2. Device

Type of 510(k) submission: Traditional
Device Name: Medical Diode Laser
Model: UTU3-F7B, UTU3-F7W, UTU3-G7B, UTU3-G7W,UTU-G20B, UTU-G20W
Device Classification Name: Laser, Dental, Soft Tissue
Regulation: 878.4810 - Laser surgical instrument for use in general and plastic surgery and in dermatology
Medical Specialty: General & Plastic Surgery
Regulatory Class: II
Primary Product Code: NVK
Secondary Product Code: GEX, ILY

3. Predicate Device

Item	Predicate Device	Reference Devices	
510(k) Number	K210367	K232222	K163128

Trade Name	D-Laser Blue, D-Laser 16	Primo Dental Laser	Epic Pro
Submitter	Guilin Woodpecker Medical Instrument Co., Ltd.	Medency S.R.L.	Biolase, Inc
Product Code	NVK,GEX, ILY	NVK,GEX	GEX

4. Device Description

The UTU series Medical Diode Laser(UTU3-F7B, UTU3-F7W, UTU3-G7B, UTU3-G7W,UTU-G20B and UTU-G20W) is a surgical and therapeutic device designated for a wide variety of oral soft tissue procedures and dental whitening as well as for use in providing a temporary relief of minor pain.The device utilizes a solid state diode as laser energy source.The energy is delivered to the operating area by means of a delivery system consisting of a flexible fiber connecting the laser source and the handpiece. The device is activated by means of a footswitch.

It is a portable medical device composed of a main unit, a laser delivery system， a footswitch, a power adapter and protective goggles.The main unit incorporates an LCD touchscreen for the device user to set output parameters and for control of the device,and a built-in large-capacity rechargeable lithium battery with longer time of endurance.The laser delivery system includes a fiber optic cable, handpiece and tips(disposable fiber tips,whitening tip,biostimulation tip or therapy tip) designed and optimized for different applications.

The UTU3-F7B and UTU3-F7W employ the diodes with wavelengths of 810nm, 650nm and 450nm, they only different in enclosure color, the enclosure color of UTU3-F7B is black and the enclosure color of UTU3-F7W is white.The UTU3-G7B and UTU3-G7W employ the diodes with wavelengths of 980nm, 650nm and 450nm, they only different in enclosure color, the enclosure color of UTU3-G7B is black and the enclosure color of UTU3-G7W is white. The UTU-G20B and UTU-G20W employ the diode with wavelength of 980nm,they only different in enclosure color, the enclosure color of UTU-G20B is black and the enclosure color of UTU-G20W is white.The device emits laser output energy in the infrared, red and blue spectra respectively.

5. Indications for Use

The UTU series Medical Diode Laser are intended for intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and inter-dental and epithelial lining of free gingiva and are indicated for: frenectomy; frenotomy; biopsy; operculectomy; implant recovery; gingivectomy; gingivoplasty; gingival troughing; crown lengthening; hemostasis of

donor site; removal of granulation tissue; laser assisted flap surgery; debridement of diseased epithelial lining; incisions and draining of abscesses; tissue retraction for impressions; papillectomy; vestibuloplasty; excision of lesions; exposure of unerupted/partially erupted teeth; removal of hyperplastic tissues; treatment of aphthous ulcers; leukoplakia; laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index,gingival bleeding index, probe depth, attachment loss and tooth inability); pulpotomy; pulpotomy as adjunct to root canal therapy; fibroma removal; gingival incision and excision; treatment of canker sores; herpetic ulcers of the oral mucosa; laser soft tissue curettage; reduction of gingival hypertrophy.

Whitening: The UTU series Medical Diode Laser are indicated for light activation for bleaching materials for teeth whitening and for laser-assisted whitening/bleaching of teeth.

Low Level Laser Therapy: The UTU series Medical Diode Laser are intended to emit energy in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.

6. Comparison to the Predicate Device

The UTU series Medical Diode Laser ,has been compared to the D-Laser Blue, D-Laser 16 (K210367), Primo Dental Laser(K232222) and Epic Pro(K163128) as reference for substantial equivalence. A table comparing the predicate devices to the subject device is shown as the following:

Table 6.1: Indications for Use

Proposed Device	**Predicate Device**	**Reference Devices**	
Wuhan Pioon Medical Diode Laser (To be decided)	**Guilin Woodpecker D-Laser Blue, D-Laser 16 (K210367)**	**Medency S.R.L. Primo Dental Laser (K232222)**	**Biolase, Inc Epic Pro (K163128)**
Surgical Indication for Use			
Intended for intraand extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and inter	Intended for intraand extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue including marginal and inter	Incision, excision, vaporization, ablation and coagulation of oral soft-tissues including marginal and inter dental gingival and	Intended for incision, excision, vaporization, ablation, hemostasis, or coagulation of intraoral and extraoral soft tissue (including marginal

dental and epithelial lining of free gingiva and is indicated for:	dental and epithelial lining of free gingiva and is indicated for:	epithelial lining of free gingiva and the following specific indications:	and interdental gingiva and epithelial lining of free gingiva); examples include:
frenectomy; frenotomy;	frenectomy; frenotomy;	frenectomy; frenotomy;	frenectomy; frenotomy;
biopsy; operculectomy;	biopsy; operculectomy;	excisional and incisional Biopsies; operculectomy;	biopsy; operculectomy;
implant recovery;	implant recovery;	implant recovery;	implant recovery;
gingivectomy; gingivoplasty	gingivectomy; gingivoplasty	gingivectomy; gingivoplasty	gingivectomy; gingivoplast
gingival troughing;	gingival troughing;	gingival troughing for crown impressions	gingival troughing;
crown lengthening;	crown lengthening;	soft-tissue crown lengthening	crown lengthening;
hemostasis of donor site;	hemostasis of donor site;	hemostasis and coagulation	hemostasis of donor site;
removal of granulation tissue;	removal of granulation tissue;	N/A	removal of granulation tissue;
laser assisted flap surgery;	laser assisted flap surgery;	N/A	laser assisted flap surgery;
debridement of diseased epithelial lining;	debridement of diseased epithelial lining;	N/A	debridement of diseased epithelial lining;
incisions and draining of abscesses;	incisions and draining of abscesses;	incision and drainage of abscess	incisions and draining of abscesses;
tissue retraction for impressions;	tissue retraction for impressions;	tissue retraction for impressions;	tissue retraction for impressions;
papillectomy; vestibuloplasty;	papillectomy; vestibuloplasty;	oral papillectomies; vestibuloplasty;	papillectomy; vestibuloplasty;
excision of lesions;	excision of lesions;	N/A	excision of lesions;
exposure of unerupted/partially erupted teeth;	exposure of unerupted/partially erupted teeth;	exposure of unerupted teeth	exposure of unerupted/partially erupted teeth;
removal of hyperplastic tissues;	removal of hyperplastic tissues;	N/A	removal of hyperplastic tissues;
treatment of aphthous ulcers;	treatment of aphthous ulcers;	treatment of aphthous ulcers of the oral mucosa;	treatment of aphthous ulcers;
leukoplakia;	leukoplakia;	leukoplakia;	leukoplakia;
pulpotomy; pulpotomy as	pulpotomy; pulpotomy as	pulpotomy; pulpotomy as	pulpotomy; pulpotomy as

adjunct to root canal therapy;	adjunct to root canal therapy;	adjunct to root canal therapy;	adjunct to root canal therapy;
fibroma removal; gingival incision and excision;	fibroma removal; gingival incision and excision;	fibroma removal;gingival incision and excision	N/A
treatment of canker sores; herpetic ulcers of the oral mucosa;	treatment of canker sores; herpetic ulcers of the oral mucosa;	treatment of canker sores; herpetic ulcers of the oral mucosa;	N/A
laser soft tissue curettage;	laser soft tissue curettage;	laser soft tissue curettage;	N/A
reduction of gingival hypertrophy.	reduction of gingival hypertrophy.	reduction of gingival hypertrophy	N/A
Laser Periodontic Indications for Use			
laser removal of diseased, infected, inflamed and necrosed soft tissue; within the periodontal pocket;	laser removal of diseased, infected, inflamed and necrosed soft tissue; within the periodontal pocket;	laser removal of diseased, infected, inflamed and necrosed soft-tissue within the periodontal pocket	N/A
sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability);	sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability);	sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth inability);	sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket)
Tooth Whitening Indications for Use			
Light activation for bleaching materials for teeth whitening;	Light activation for bleaching materials for teeth whitening;	light activation for bleaching materials for teeth whitening	Light activation for bleaching materials for teeth whitening.
Laser-assisted whitening/bleaching of teeth.	Laser-assisted whitening/bleaching of teeth.	laser-assisted whitening/bleaching of teeth	N/A
Low Level Laser Therapy Indications for Use			
Intended to emit energy in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle	Intended to emit energy in the red and infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor	Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains,	N/A

spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.	arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.	and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.	

Table 6.2: Technological Characteristics

Item	**Proposed Device**	**Predicate Device**	**Reference Devices**	
510(k) Number	/	K210367	K232222	K163128
Trade Name	Medical Diode Laser	D-Laser Blue, D-Laser 16	Primo Dental Laser	Epic Pro
Product Code	NVK,GEX, ILY	NVK,GEX, ILY	NVK,GEX	GEX
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Classification	II	II	II	II
Application	Dental laser	Dental laser	Dental laser	Dental laser
Laser Classification	980 nm,810nm and 450nm Laser: Class IV 650 nm Laser: Class II	976 nm and 450nm Laser: Class IV 650 nm Laser: Class II	980 nm, 940 nm,810 nm and 450nm Laser: Class IV 635 nm Laser: Class II	Class IV
Laser Type	Diode laser	Diode laser	Diode laser	Diode laser
Laser Wavelength	980±20nm 810±10nm 650 nm±20nm 450 nm±10nm	976 nm (+/-20 nm); 650 nm (+/-20 nm); 450 nm (+/-20 nm);	450±10nm 810±10nm 940±10nm 980±10nm (635+810+980) nm (450+635+810) nm (450+635+980) nm	980±20nm
Optical Power	UTU3-G7B/UTU3-G7W 980nm: 0.1 W -7 W (Continuous Wave) UTU-G20B/UTU-G 20W 980nm: 0.1 W -20W (Continuous Wave) 810 nm:	D-Laser Blue 976nm: 0.2 W – 4 W (Continuous Wave) 7 W (peak power); D-Laser 16 976nm: 0.3 W – 7 W (Continuous Wave) 16 W (peak power); 650 nm:	Max.10W	0.2 W - 25 W

	0.1 W -7W (Continuous Wave) 650 nm: 25 mW-200 mW (Continuous Wave) 450 nm: 0.1 W -3.0 W (Continuous Wave)	25 mW-200 mW (Continuous Wave) 450 nm: 0.2 W - 3.0 W (Continuous Wave) 4 W (peak power)		
Operation Mode	Continuous Wave; Pulse	Continuous Wave; Pulse	Continuous Wave; Pulse	Continuous Wave; Pulse
Pulse Duration	25μs – 999 ms	5 μsec. To 0.9 sec.	Not known	10μs-100ms
Repetition Rate	0.5 Hz – 20 kHz	1 Hz – 20 kHz	Up to 20 kHz	Up to 20 kHz
Aiming Beam	650±20 nm, Pmax＜ 2 mW	650±20 nm, Pmax＜5 mW	650±20 nm	650nm,5mW (max.)
User Interface	Color touch screen graphical user interface	Color touch screen graphical user interface	Color touch screen graphical user interface	Color touch screen graphical user interface
Activation Method	Footswitch	Footswitch	Footswitch	Footswitch
Delivery System	Fiber optic cable , handpiece, accessories.	Fiber optic cable , handpiece,accessories.	Fiber optic cable , handpiece ,accessories.	Fiber optic cable , handpiece ,accessories.
Optical Fiber Surgical Tips	Fiber Diameter: 200 μm, 300 μm, 400 μm	Fiber Diameter: 200 μm, 300 μm, 400 μm	Fiber Diameter: 200 - 400 μm	Fiber Diameter: 300 μm, 400 μm
	Single-use tips. Provided non-sterile.	Single-use tips. Provided non-sterile.	Single-use tips. Provided non-sterile.	Single-use tips. Provided non-sterile.
Curved Light Guide	Biostimulation Tip (8 mm diameter)	N/A	Biostimulation handpiece (8 mm diameter)	N/A
Whitening Tip	45mmx7mm	Not known	Whitening handpiece (40mmx10mm)	Not known
Therapy Tip	18mm diameter	Not known	Bell therapy handpiece (10mm diameter)	N/A

Patient-contacting Materials	1) Handpiece: Aluminium alloy 2) Disposable fiber tips: Stainless steel, quartz and PP (Polypropylene) 3) Whitening tip: Aluminium alloy，ACRYLIC 4) Biostimulation tip: Aluminium alloy, Glass 5) Therapy tip: Aluminium alloy	1) Handpiece: Stainless steel 2) Disposable fiber tips: Stainless steel, quartz and PP (Polypropylene) Not public for other components.	Quartz fiber tips; Not public for other components.	Quartz fiber tips; Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components
Biocompatibility	Comply with ISO 10993-1, Tests included Cytotoxicity, Sensitization and Irritation	Comply with ISO 10993-1, Tests included Cytotoxicity, Sensitization and Irritation	Comply with ISO 10993-1, Tests included Cytotoxicity, Sensitization and Irritation	Comply with ISO 10993-1, Tests included Cytotoxicity, Sensitization and Irritation

From above two tables, the proposed devices UTU series Medical Diode Laser and the predicate devices D-Laser Blue and D-Laser 16 have the same indications for use respectively.The subject device uses similar 450nm,650nm,810nm and 980nm diode lasers technology as that used by the predicates. The output parameters of the proposed device are similar to the output parameters of the predicates, and subtle differences in the output parameters do not raise new types of questions regarding the safety and effectiveness when the device is used for the proposed indications for use. Although the patient-contacting materials of the subject device is different from the predicate device, we conducted the biocompatibility tests according to ISO 10993-5, ISO 10993-10 and ISO 10993-23 on all the patient contact accessories of subject device, and all test results are in compliance with standards' requirements. So the difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

7. Performance Data

Clinical data:

Not applicable.

Non-clinical data:

Biocompatibility Testing

The biocompatibility evaluation of the submitted device was conducted in accordance with "ISO 10993-1 Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing within a Risk Management Process". The following Cytotoxicity, Sensitization and Irritation biological tests were performed on all the patient contact accessories : the results demonstrate biocompatibility.

• ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.

• ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization.

• ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation.

Electrical Compatibility and Electrical Safety

The Medical Diode Laser was tested and found to conform to the criteria of the following performance standards:

• IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

• IEC 60601-1-2:2014+A1:2020 (Fourth Edition) Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: electromagnetic disturbances – Requirements and tests.

Performance Testing – Bench

The Guidance Document, Laser Products – Conformance with IEC 60825-1 and IEC 60601-2-22 (Laser Notice 56) January 19, 2018 was used. Pioon has conducted functional and system level testing to validate the performance of the devices. The results of the bench testing show that the subject device meets its accuracy specifications and meets relevant consensus standards.

• IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification, and requirements.

• IEC 60601-2-22:2019 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

• IEC 80601-2-60:2019 Medical Devices Part 2: Particular requirements for the basic safety and essential performance of dental equipment.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Function".

The recommended Documentation Level for software of this device was considered as a "Basic Documentation Level " and the documentation was provided accordingly.

8. Conclusions

The non-clinical data support the safety of the proposed UTU series Medical Diode Laser device, and the software verification and validation demonstrate that the device can perform as intended. The proposed device uses similar laser diode technology as that used by the predicate devices and difference in parameters do not raise new types of questions regarding safety and effectiveness for the proposed indications for use. The UTU series Medical Diode Laser is considered to be substantially equivalent to the predicate devices.