November 15, 2022

Canadian Pioneer Medical Technology Corporation (CPMT LASER)
Rashid Sayah
Managing Director
210 Drumlin Circle #2, Concord
Vaughan, Ontario L4K 3E3
Canada

Re: K222915
Trade/Device Name: Quadruple Laser System , Models : CPMT ARES , CPMT NEMESIS , CPMT NYX PLUS , CPMT GRACE PLUS
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: September 26, 2022
Received: September 26, 2022

Dear Rashid Sayah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jianting Wang -S

Jianting Wang
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K222915

Device Name

Quadruple Laser System , Models : CPMT ARES . CPMT NEMESIS , CPMT GRACE PLUS , CPMT NYX PLUS

Indications for Use *(Describe)*

The Quadruple Laser System has 4 types of handles : 755 nm , 808nm and 1064 nm and simultaneous triple wavelength 755/808/1064nm .

Intended Use
The device is intended for use in dermatologic and general surgical procedures.

The simultaneous triple wavelength handpiece is intended for use in dermatology procedures requiring coagulation. The indications for use for the Triple wavelength handpiece include:
Benign vascular and vascular dependent lesions removal.

The indications for use for the handpiece of 1064nm include:

- The Hair Removal is intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen.
- Treatment of Pseudo folliculitis Barbae (PFB)
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.

The indications for use for the handpiece of 808 nm include:

- The Hair Removal (HR) is intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen.
- The treatment of benign vascular and pigmented lesions.
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.

The indications for use for the handpiece of 755 nm include:

- The Hair Removal (HR) is intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen.
- The treatment of benign vascular and pigmented lesions.
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) summary

K222915

I Submitter

Canadian Pioneer Medical Technology Corporation (CPMT LASER)
210 Drumlin Circle#2 , Vaughan, Ontario, L4K 3E3, Canada

Contact person:
Dr. Rashid Reza Mir Sayah
Managing Director
Phone: 4377727788
Email:
Canadianpioneer@yahoo.com
Canadianpioneermedical@gmail.com
Date of preparation: Sep 17, 2022

II Subject Device

Trade Name of Device: The Quadruple Laser System, Model: CPMT Nyx Plus , CPMT Grace Plus, CPMT ARES, CPMT NEMESIS
Common name: Powered Laser Surgical Instrument
Regulation Number: 21 CFR 878.4810
Regulatory Class: II
Product code: GEX
Review Panel: General & Plastic Surgery

III Predicate Devices

1.
Trade Name of Device: Nyx plus , Grace Plus , Ares , Nemesis
Common name: Powered Laser Surgical Instrument
Regulation Number: 21 CFR 878.4810
Regulatory Class: II
Product code: GEX
Review Panel: General & Plastic Surgery
510(k) number: K211722
2.
Trade Name of Device:
Modified Alma Lasers Soprano XLTM Family of Multi-Application and Multi-Technology Platforms [SopranoXL, SopranoXLi, Soprano ICE and Soprano ICE Platinum] with Trio Diode Laser Module

Common name: Powered Laser Surgical Instrument
Regulation Number: 21 CFR 878.4810
Regulatory Class: II
Product code: GEX
Review Panel: General & Plastic Surgery
510(k) number: K172193

IV Device description

The Quadruple Laser System consists of the main unit and a hand piece. The system uses a diode laser as an active medium placed in an optical cavity to produce amplified beam. A microprocessor is used to control electronics for the front panel. A self-contained water cooling system is built into the power supply unit.

The Laser treatment device is designed to be used in dermatological practice for stable, long term hair reduction. The principle of laser hair removal is selective photothermolysis. The wavelength of 808nm, 755, and 1064nm would be able to effectively penetrate deep into and absorbed by the target chromophore. The laser power is delivered to the treatment region via a delivery system.

The proposed device includes power supply system, delivery system, control system, cooling system, laser system.

The 755nm, 808 nm, 1064nm handpieces with different treatment sizes are available for different models.

V Indications for use

The Quadruple Laser System has 4 types of handles : 755 nm , 808nm and 1064 nm and simultaneous triple wavelength 755/808/1064nm .

Intended Use

The device is intended for use in dermatologic and general surgical procedures..

The simultaneous triple wavelength handpiece is intended for use in dermatology procedures requiring coagulation. The indications for use for the Triple wavelength handpiece include:

Benign vascular and vascular dependent lesions removal.

The indications for use for the handpiece of 1064nm include:

- The Hair Removal is intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen.
- Treatment of Pseudo folliculitis Barbae (PFB)
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.

The indications for use for the handpiece of 808 nm include:
- The Hair Removal (HR) is intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen.
- The treatment of benign vascular and pigmented lesions.
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.

The indications for use for the handpiece of 755 nm include:
- The Hair Removal (HR) is intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen.
- The treatment of benign vascular and pigmented lesions.
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.

VI Comparison of technological characteristics with the predicate devices

The indication of proposed device is covered by the predicated devices. The proposed device is intended to use for hair removal on all skin types and Benign Vascular lesions and vascular dependent lesions removal.

The device includes four models for clearance in this submission. The differences between models are on their appearance and number of the connectors.These models are covered by the predicated devices.

Device feature	**Quadruple Laser System models CPMT Nyx plus, CPMT Grace plus, CPMT Nemesis, CPMT Ares (K222915)**	**Laser treatment system , models Nyx plus, Grace plus, Nemesis, Ares (K211722)**	**Alma Lasers Soprano family (K172193)**
Product code	GEX	GEX	GEX
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Manufacturer	CPMT LASER (Canadian Pioneer Medical Technology Corporation)	CPMT LASER (Canadian Pioneer Medical Technology Corporation)	Alma Lasers Inc.
Indications for use: **The Simultaneous Triple Wavelength Handpiece (755/808/1064)nm**	intended for use in dermatology procedures requiring coagulation. The indications for use for the Triple wavelength handpiece include: ● Benign vascular and vascular dependent	intended for use in dermatology procedures requiring coagulation. The indications for use for the Triple wavelength handpiece include: ● Benign vascular and vascular dependent	intended for use in dermatology procedures requiring coagulation. The indications for use for the Triple wavelength handpiece include: ● Benign vascular and vascular dependent

	lesions removal.	lesions removal.	lesions removal.
The indications for use for the **Handpiece of 1064nm**	● The Hair Removal is intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regimen. ● Treatment of Pseudo folliculitis Barbae (PFB) ● Use on all skin types (Fitzpatrick I-VI), including tanned skin.	N/A	● Permanent reduction in hair regrowth in HR and SHR Mode ● Treatment of Pseudo folliculitis Barbae (PFB) ● Use on all skin types (Fitzpatrick I-VI), including tanned skin
The indications for use for the **handpiece of 808 nm**	● The Hair Removal (HR) is intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regimen. ● The treatment of benign vascular and pigmented lesions. ● Use on all skin types (Fitzpatrick I-VI),	N/A	**(810nm)**: ● The Hair Removal (HR) and Super Hair Removal (SHR) Mode are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen. ● The treatment of benign vascular and pigmented

	including tanned skin.		lesions.(The Laser Blanch (LB) Mode) ● Use on all skin types (Fitzpatrick I-VI), including tanned skin. (HR, SHR and LB Modes)
The indications for use for the **Handpiece of 755 nm**	The Hair Removal (HR) is intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen. - The treatment of benign vascular and pigmented lesions. - Use on all skin types (Fitzpatrick I-VI), including tanned skin.	N/A	● The Hair Removal (HR) and Super Hair Removal (SHR) Mode are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen. ● The treatment of benign vascular and pigmented lesions.(The Laser Blanch Mode) ● Use on all skin types (Fitzpatrick I-VI), including tanned skin.(HR, SHR and Laser Blanch Modes)
Laser classification	Class IV	Class IV	Class IV
755nm handpiece	Laser medium: Semi conductor Spot size: 12*12 mm (optional 15*27 mm)	N/A	Laser medium: solid state Spot size: 15*10mm (1.5cm2) Pulse duration: 3.3-200ms

	Pulse duration: 1-400 ms Energy density (fluence): Up to 120 J/cm^2 at 12*12 mm (Fluence up to 42 J/cm^2 at optional 15*27 mm) Repetition rate: 0.5-10 Hz		Energy density (fluence) [HR]: 2-120 J/cm^2 Repetition rate [HR]: 0.5-3 Hz
808nm nm handpiece	Laser medium: Semi conductor Spot size: 12*12 mm (optional 15*27 mm) Pulse duration: 1-400 ms Energy density (fluence): Up to 120 J/cm^2 at 12*12 mm (Fluence up to 42 J/cm^2 at optional 15*27 mm) Repetition rate: 0.5-10 Hz	N/A	**(810**nm): Laser medium: solid state Spot size: 12*10mm (1.2cm^2) 20*10 mm (2cm^2) Pulse duration: 3.3-200ms Energy density (fluence) [HR]: 2-120 J/cm^2 Frequency [HR]: 0.5-3 Hz
1064nm wavelength	Laser medium: Semi conductor Spot size: 12*12 mm (optional 15*27 mm) Pulse duration: 1-400 ms Energy density (fluence): Up to 120 J/cm^2 at 12*12 mm (Fluence up to 42 J/cm^2 at optional 15*27 mm)	N/A	Laser medium: Solid state Spot size: 10mm*10mm (1cm2) ; Optional tapered tip 6mm (0.28 cm2) Pulse duration: 3.3-280ms Energy density (fluence) [HR]: 2-120 J/cm^2 Frequency: 0.5-3 Hz (HR), 5-10 Hz(SHR); 2 Hz(LB)

	Repetition rate: 0.5-10 Hz		
Simultaneous triple-wavelength handpiece (755/808/1064nm)	Spot size: 12*12 mm (optional 15*27 mm) Pulse duration: 1-400ms Energy density (fluence): Up to 120 J/cm^2 at 12*12 mm (Fluence up to 42 J/cm^2 at optional 15*27 mm) Repetition rate: 0.5-10 Hz	Spot size: 12*12 mm (optional 15*27 mm) Pulse duration: 5-300ms (400 optional) Energy density (fluence): Up to 120 J/cm^2 Repetition rate: 1-10 H	755/**810**/1064 nm (Trio): Spot size: n/a Pulse duration: n/a Energy density (fluence): n/a Repetition rate: n/a
Power supply	100-240V AC, 50/60Hz	100-240V AC, 50/60Hz	100-240V AC, 50/60Hz
Biocompatibility	Comply with ISO10993-1	Comply with ISO10993-1	Comply with ISO10993-1
Electrical Safety	Comply with IEC60601-1, IEC60601-2-22	Comply with IEC60601-1, IEC60601-2-22	Comply with IEC60601-1, IEC60601-2-22
EMC	Comply with IEC60601-1-2	Comply with IEC60601-1-2	Comply with IEC60601-1-2
Laser safety	Comply with IEC60825-1, IEC60601-2-22	Comply with IEC60825-1, IEC60601-2-22	Comply with IEC60825-1, IEC60601-2-22

VII Performance data

The following performance data were provided in support of the substantial equivalence

determination.

Biocompatibility testing

Biocompatibility of the Laser Treatment System was evaluated in accordance with ISO 10993-1:2009 for the body contact category of “Surface –intact skin” with a contact duration of “Limited (< 24 hours)”. The following tests were performed, as recommended: Cytotoxicity, Irritation and Sensitization. All evaluation acceptance criteria were met

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Laser Treatment System. The system has been tested to comply with the following standards:

- IEC 60601-1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- IEC 60601-2-22:2007, Medical Electrical Equipment - Part 2-22: Particular Requirements For Basic Safety And Essential Performance Of Surgical, Cosmetic, Therapeutic And Diagnostic Laser Equipment;
- IEC 60825-1: 2007, Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 60601-1-2:2007, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests.

VIII Conclusion

The Quadruple Laser System is substantially equivalent to its predicate devices. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.