February 25, 2022

Canadian Pioneer Medical Technology Corporation
Rashid Reza Mir
Sayah
Unit 2 -210 Drumlin Circle, Concord
Vaughan, Ontario L4K 3E3
Canada

Re: K211722
Trade/Device Name: Laser Treatment System, Models: Nyx Plus, Grace Plus, Ares, Nemesis
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: January 17, 2022
Received: January 19, 2022

Dear Rashid Reza Mir:

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,

Purva Pandya
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211722

Device Name
Laser Treatment System Models: Nyx Plus, Grace Plus, Ares, Nemesis

Indications for Use *(Describe)*
The Laser Treatment System, Models: Nyx Plus, Grace Plus, Ares, Nemesis, when used with the simultaneous triple wavelength module 755-808-1064 nm, is intended for :
• Benign vascular lesions and vascular dependent lesions removal

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.

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510(k) summary

I Submitter

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

Contact person:
Dr. Rashid Reza Mir Sayah
Managing Director
Phone: 4377727788
Email: Canadianpioneer@yahoo.com
Date of preparation: May 29, 2021

II Subject Device

Trade Name of Device: Laser Treatment System, Model: 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

III Predicate Device

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 Laser Treatment System consists of the main unit and its handpieces. The system uses laser as an active medium placed in an optical cavity to produce amplified beam at the applicators and the Simultaneous triple-wavelength of 755,808 and 1064 nm. 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 System is designed to be used dermatology procedures requiring coagulation. The indications for use for the 3 simultaneously wavelength 755,808,1064 nm Laser Module is treatment of benign vascular and vascular dependent lesions.

V Intended use of device and Indications for Use

Intended Use

The Laser Treatment System, Models: Nyx Plus, Grace Plus, Ares, Nemesis, when used with the simultaneous triple wavelength module 755-808-1064 nm, is intended for :

• Benign vascular lesions and vascular dependent lesions removal

VI Comparison of technological characteristics with the predicate devices

The indication of the proposed device is covered by the predicated devices. The laser treatment system includes four models of machines and the simultaneous triple wavelength applicator for all four models.

Device feature	**Laser Treatment System (subject device)**	**Modified Alma Lasers Soprano XL. Family of Multi-Application & Multi-Technology Platforms (K172193)**
Product code	GEX	GEX
Regulation number	21 CFR 878.4810	21 CFR 878.4810
Indications for use	The indication of use of 3 wavelength 755,808,1064 handpiece (trio is treatment of Benign vascular lesions and vascular dependent lesions removal	The indication of use of trio is treatment of Benign vascular lesions and vascular dependent lesions removal
Laser classification	Class IV	Class IV

Wavelength	The Simultaneous triple-wavelength laser device (trio) 755-808-1064 nm	Trio 755-808-1064 nm
Frequency	1-10Hz	0.5~3 Hz (HR), 5~10 Hz(SHR); 2 Hz(LB)
Pulse Duration	5-300 (to 400 optional)	3.3-200ms
Biocompatibility	Comply with ISO10993-1	Comply with ISO10993-1
Electrical Safety	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,
Laser safety	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;

- IC 60601-2-22: 2007 (Third Edition) + A1:2012 for use inconjunction with IEC 60601-1: 2005 (Third Edition) + A1:2012
- IEC 60825-1: 2007, Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 60601-1-2:2014, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests.

VIII Conclusion

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