February 26, 2021

Canadian Pioneer Medical Technology Corporation
Dr. Rashid Reza Mir Sayah
Managing Director
Unit 2, 210 Drumlin Circle
Concord, Vaughan, Ontario L4K 3E3 CAN

Re: K210033
Trade/Device Name: Laser Treatment System, Model: NYX and Grace
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: December 24, 2020
Received: January 5, 2021

Dear Dr. Rashid Reza Mir 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 and Part 809); 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210033

Device Name
Laser Treatment System, Model: NYX and Grace

Indications for Use *(Describe)*
The Laser Treatment System is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type 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.

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: K210033

I. Submitter

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Date of preparation: Feb.20th, 2021

II. Subject Device

Trade Name of Device: Laser Treatment System, Model: NYX and Grace
Common name: Powered Laser Surgical Instrument
Classification Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulation Number: 21 CFR 878.4810
Regulatory Class: II
Product code: GEX
Review Panel: General & Plastic Surgery

III. Predicate Devices

Trade Name of Device: Diode Laser Treatment System
Manufacturer: Weifang KM Electronics Co., LTD"
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: K182924

IV. Device description

The Laser Treatment 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 at the wavelength of 808 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 diode laser operates in a pulsed mode with a fixed pulse width and fixed pulse duration of the pulse train for each mode. The number of pulses can be adjusted within the preset range.
The Laser Treatment System includes two (2) models, NYX and Grace, the differences between them are the external shape and the numbers of the handpiece connectors, NYX is the desktop type with one handpiece connector, and Grace is vertical stand type with two handpiece connectors.

V. Indications for use

The Laser Treatment System is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type 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.

VI. Comparison of technological characteristics with the predicate devices

The Laser Treatment System has the same technological characteristics and fundamental design as the predicate device. The subject device and the predicate devices are all designed for hair removal on different parts of the body. The differences between the subject device and predicate devices do not alter suitability of the proposed device for its intended use.

Device feature	**Laser Treatment System, Model: NYX and Grace (K210033)**	**Diode Laser Treatment System (K182924)**
Manufacturer	Canadian Pioneer Medical Technology Corporation	Weifang KM Electronics Co., Ltd.
Product code	GEX	GEX
Regulation number	21 CFR 878.4810	21 CFR 878.4810
Indications for use	The Laser Treatment System is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type 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	The Diode Laser Treatment System is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type 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.	regime.
Operation principle	Melanin could absorb the energy from the laser, which would result in temperature rapid increase, to destroy surrounding hair follicles, and finally remove hair.	Melanin could absorb the energy from the laser, which would result in temperature rapid increase, to destroy surrounding hair follicles, and finally remove hair.
Laser type	Diode laser	Diode laser
Laser classification	Class IV	Class IV
Laser wavelength	808nm	808nm
Spot Size	1.44 cm^2	1.44 cm^2
Fluence	1-120J/cm^2	2-120J/cm^2
Frequency	1-10Hz	1-10Hz
Pulse Duration	10-300ms	10-300ms
Power supply	100-240V AC, 50/60Hz	100-240V AC, 50/60Hz
Patient contact material	Sapphire in handpiece and handpiece tip (stainless steel)	Sapphire in handpiece and handpiece tip (stainless steel)
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 IEC 60601-1-2,	Comply with IEC60601-1-2,
Laser safety	Comply with IEC60825-1, IEC60601-2-22	Comply with IEC60825-1, IEC60601-2-22

VII Summary of Non-clinical Performance Testing

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 60601-1-2:2014, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests.

Bench Testing

- IEC 60601-2-22:2007 + A1:2012, 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.

Software Validation and Verification Testing

The Laser Treatment System also underwent software verification and validation, with results demonstrating that the software is appropriate for release. System verification testing further confirmed that the system performs as intended, and that the energy outputs of the device meet specifications.

VIII Conclusion

The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device (K182924).