April 16, 2024

CPMT Laser (Canadian Pioneer Medical Technology Corporation)
Rashid Sayah
Managing Director
460 Garyray Drive, North York
Toronto, Ontario M9L 1P8
Canada

Re: K232133
Trade/Device Name: CO2 Laser System (Models: PureLase And VanLase)
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: March 13, 2024
Received: March 13, 2024

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 (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.

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,

Tanisha L. Hithe -S
Digitally signed by Tanisha L. Hithe -S
Date: 2024.04.16 14:35:43 -04'00'

Tanisha Hithe
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)*
K232133

Device Name
CO2 Laser System (Models: Purelase and Vanlase)

Indications for Use *(Describe)*
CO2 Laser System is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

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

K232133

This 510(k) Summary is being submitted in accordance with requirements of 21CFR Section 807.92.

I Submitter

CPMT LASER (Canadian Pioneer Medical Technology Corporation)
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Date of preparation: April 15, 2024

II Subject Device

Trade/Device Name: CO2 Laser System (Models: Purelase and Vanlase)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
Regulatory Class: II Product
code: GEX
Manufacturer: Canadian Pioneer Medical Technology Corporation

III Predicate Device

Trade/Device Name: EdgeOne CO2 Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
Regulatory Class: II
Product code: GEX
510(k) number: K162169
Manufacturer: Jeisys Medical Inc.

IV Device description

The CO2 Laser System is a computer controlled radiofrequency (RF) excited carbon dioxide (CO2) laser system that delivers CO2 energy to the target treatment area at 10,600 nm. The CO2 Laser System is comprised of multiple components, including the control unit and handpieces. Laser is transmitted to the tissue via a series of lenses integrated into the

articulated arm. The CO2 laser energy is absorbed by water in tissue to achieve its intended treatment effects.

V Indications for use

CO2 Laser System is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology(ENT), gynaecology, neurosurgery, orthopaedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

VI Substantial Equivalence Comparison

Comparison of the Indications for Use: The indications for use of the subject device is comparable to the indications for use of the predicate device.

Comparison of technology:

Device & Predicate Device(s):	K232133	K162169
General Device Characteristics		
Laser	CO2	CO2
Wavelenghts (nm)	10600	10600
Power Output (W)	1-30 W	≤ 30W
Pulse Duration	1-1000 ms	1-1000 ms
Repetition Rate (Hz)	1-500	10-500
Scan Area (mm^2)	1x1 – 20x20	15 X 15
Surgical Handpieces (μm)	μablative tip: 350-500 non-ablative tip: 800-1200	150, 1000
Beam Divergence	7.5±0.5 mrad	Unavailable

VII Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device. The following tests were conducted:

- IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety and Essential Performance.
- IEC 60601-2-22, 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, Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 60601-1-2 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility-Requirements and tests.
- Biocompatibility Performance per ISO 10993 and FDA Guidance
- Software Verification and Validation
- Bench Testing

VIII Conclusion

Based on the comparison and analysis above, the proposed subject device is determined to be Substantially Equivalent (SE) to the predicate device.