December 26, 2024

JiangXi Medex Technology Co., Ltd
℅ Owen He
Consultant
Microkn Medical Technology Service (Shanghai) Co., Ltd.
Room 901, No.889, Pinglu Road, Jing'an District
Shanghai,
China

Re: K243141
Trade/Device Name: Diode Laser System (LaserPro D 980); Diode Laser System (LaserPro D 810); Diode Laser System (Aurolance 980); Diode Laser System (Aurolance 810); Diode Laser System (Aurolance AM)
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: July 20, 2024
Received: September 30, 2024

Dear Owen He:

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,

Shlomit Halachmi -S

Digitally signed by Shlomit Halachmi -S
Date: 2024.12.26 13:20:15 -05'00'

For 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243141

Device Name
Diode Laser System (LaserPro D 980); Diode Laser System (LaserPro D 810); Diode Laser System (Aurolance 980); Diode Laser System (Aurolance 810); Diode Laser System (Aurolance AM)

Indications for Use *(Describe)*
Diode Laser System, (and the fiber delivery systems and accessories used to deliver laser energy), are indicated for use in surgical applications requiring the hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), ophthalmology, arthroscopy, podiatry, pulmonology, and thoracic surgery; and Laser Assisted Lipolysis (980 nm only). Diode Laser System, (and the fiber delivery systems and accessories used to deliver laser energy), are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: orthopedics.

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) #: K243141

510(k) Summary

Prepared on: 2024-11-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	JiangXi Medex Technology Co.,Ltd
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Correspondent Name	Microkn Medical Technology Service (Shanghai) Co., Ltd.
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Correspondent Contact Telephone	+86 13795451145
Correspondent Contact	Mr. Owen He
Correspondent Contact Email	fda@microkn.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Diode Laser System (LaserPro D 980); Diode Laser System (LaserPro D 810); Diode Laser System (Aurolance 980); Diode Laser System (Aurolance 810); Diode Laser System (Aurolance AM)
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Powered Laser Surgical Instrument
Regulation Number	878.4810
Product Code(s)	GEX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K082721	LASERPRO 810, 940 AND 980 DIODE LASER SYSTEMS	GEX
K952754	SACS, INDEPENDENT FIBER COOLANT SYSTEM	GEX

Device Description Summary

21 CFR 807.92(a)(4)

The Aurolance AM diode laser system consists of a unit, footswitch, power cord assembly, unit key, and protective eyewear.

The Aurolance 980 diode laser system consists of a main unit, footswitch, power cord assembly, unit key and protective eyewear.
The Aurolance 810 diode laser system consists of a unit, footswtich, power cord assembly, unit key and protective eyewear.
The LaserPro D980 diode laser system consists of a main unit, footswtich, power cord assembly, unit key, and protective eyewear.
The LaserPro D810 diode laser system consists of a main unit, footswitch, power cord assembly, unit key and protective eyewear.

The fiber delivery systems are not included in this submission

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Diode Laser System, (and the fiber delivery systems and accessories used to deliver laser energy), are indicated for use in surgical applications requiring the hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), ophthalmology, arthroscopy, podiatry, pulmonology, and thoracic surgery; and Laser Assisted Lipolysis (980 nm only). Diode Laser System, (and the fiber delivery systems and accessories used to deliver laser energy), are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: orthopedics.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indication for use is the same with predicate devices.

Technological Comparison

21 CFR 807.92(a)(6)

The purposed device and the predicated device are same in product code, regulation number,the indications for use, Laser type, Laser output power, Laser Class, Instability of laser output, Pulse Duration, Laser mode, SACS operating mode, SACS output flow. There is minor difference in wavelength. But these differences will not result in differences on safety and performance between purposed device and the predicated device. Details of the performance characteristics are shown as below:
Laser type: Diode Laser (Same as the predicated device)
Laser output power: Working beam: 810 nm: Maximum 25W, Aiming beam: 650 nm: ≤ 5mW (Same as the predicated device)
Wavelength: 980 nm, 810nm (The wavelength of predicated device is about 980nm, 810nm and 940 nm,there is minor difference)
Pulse Duration:
Laser pulse width: Should be 0.05s~99s, with an error of ±10%.
Pulse interval: Should be between 0.01s and 99s, with an error of ± 10%. (Same as the predicated device)
Laser Class: Class IV (Same as the predicated device)
Instability of laser output: Should be better than±5% (Same as the predicated device)
Laser mode: Should be multimode (Same as the predicated device)
SACS operating mode: Air, carbon dioxide (CO2) or liquid working modes for model, Aurolance 980, Aurolance 810, Aurolance AM, Air, carbon dioxide (CO2) for model LaserPro D980, LaserPro D810 (Same as the predicated device)
SACS output flow: Air output flow: adjustable range: 0.2 l/min-1.4 l/min; step value: 0.1 l/min;
Carbon dioxide (CO2) output flow: adjustable range: 0.2 l/min-1.4 l/min; step value: 0.1 l/min.;
Liquid output flow: adjustable range: 2ml/min-16ml/min; step value: 1ml/min (Same as the predicated device)

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical Testing
The bench testing of Diode Laser System and non-clinical testing is performed on new devices is to demonstrate the substantial equivalence to the predicate devices. Tests setup and execution are performed in accordance with applicable standards. Results of the testing demonstrate the compliance to the standards and matching the performance of new devices to the predicate devices. The following performance data were provided in support of the substantial equivalence determination.

Safety and Performance test
The proposed device has been tested on according to IEC 60601-1: 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 and IEC 60825-1: Safety of laser products -Part 1: Equipment classification and requirements. The safety and performance of device meet the requirements.

EMC test
The proposed device has been tested on according to
IEC 60601-1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic disturbances-Requirements and tests. The EMC property meets the requirements.

IEC/TR 60601-4-2: 2016 Medical electrical equipment - Par4.2: Guidance and interpretation - electromagnetic immunity: performance of medical electrical equipment and medical electrical systems The Diode Laser System is substantially equivalent to the predicate devices.