February 27, 2026

Beijing HuaCheng Taike Technology Co., Ltd.
℅ Lena Zhang
RA Manager
Tianjin Xinnuocheng Medical Technology Co., LTD.
Rm. 1505, Wanhai Bldg., Dazhigu Sub-District
Hedong District
Tianjin, 300170
China

Re: K253828
Trade/Device Name: Medical Alexandrite and Nd:YAG laser Therapy System (CM11LP)
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: November 28, 2025
Received: December 1, 2025

Dear Lena Zhang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2026.02.27 17:53:39 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253828

Device Name
Medical Alexandrite and Nd:YAG laser Therapy System (CM11LP)

Indications for Use *(Describe)*
The Medical Alexandrite and Nd:YAG laser Therapy System is indicated for the following at the specified wavelength:
755nm
• Temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime. 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. On all skin types (Fitzpatrick I- VI) including tanned skin.
• Treatment of benign pigmented lesions.
• Treatment of wrinkles.
• The photocoagulation of dermatological benign vascular lesions (such as portwine stains, hemangiomas, telangiectasias)
1064nm
• Removal of unwanted hair, for stable long term or permanent hair reduction. 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. The lasers are indicated on all skin types Fitzpatrick I-VI including tanned skin. Benign pigmented and/or benign vascular lesions, such as, but not limited to port-wine stains, telangiectasia, venus lake, leg veins and spider veins. Benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratosis, nevi, chloasma, skin tags, keratosis.
• Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
• Treatment of wrinkles.
• Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.)

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.

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"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."

The assigned 510(k) Number: K253828

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Preparation: 2025/11/28

2. Sponsor Identification

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3. Designated Submission Correspondent

Ms. Lena Zhang

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4. Identification of Proposed Device

Trade Name: Medical Alexandrite and Nd:YAG laser Therapy System

Model: CM11LP

Common Name: Powered Laser Surgical Instrument

Regulatory Information

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Classification: II

Product Code: GEX

Regulation Number: 878.4810

Review Panel: General & Plastic Surgery

5. Identification of Predicate Device(s)

Predicate device:
510(k) Number: K200110
Product Name: SANDRO Dual
Manufacturer: WON TECH Co., Ltd.

6. Device Description

The Medical Alexandrite and Nd:YAG laser Therapy System is a Nd: YAG and Alexandrite laser operating at wavelengths of 1064 nm and 755 nm. The Medical Alexandrite and Nd:YAG laser Therapy System consists of the main unit, optical fiber, handpiece, treatment tip, footswitch, and handpiece holder and other accessories. The laser output is delivered to the skin through the optical fiber terminated by the handpiece. The Medical Alexandrite and Nd:YAG laser Therapy System is used for a variety of medical purpose. For treatment, the user can select the appropriate wavelength and the related output energy value by pressing UP and/or DOWN buton from the LCD display/Touch Pad located on the front of the main unit.

7. Indication For Use Statement:

The Medical Alexandrite and Nd:YAG laser Therapy System is indicated for the following at the specified wavelength:

755nm

Temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime. 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. On all skin types (Fitzpatrick I- VI) including tanned skin.

Treatment of benign pigmented lesions.

Treatment of wrinkles.

The photocoagulation of dermatological benign vascular lesions (such as portwine stains, hemangiomas, telangiectasias)

1064nm

Removal of unwanted hair, for stable long term or permanent hair reduction. 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. The lasers are indicated on all skin types Fitzpatrick I-VI including tanned skin. Benign pigmented and/or benign vascular lesions, such as, but not limited to port-wine stains, telangiectasia, venus lake, leg veins and spider

veins. Benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratosis, nevi, chloasma, skin tags, keratosis.

Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

Treatment of wrinkles.

Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.)

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	Proposed Device	Predicate Device K200110	Remark
Device name	Medical Alexandrite and Nd:YAG laser Therapy System	SANDRO Dual	/
Classification Regulation	21 CFR 878.4810	21 CFR 878.4810	SAME
Classification	II	II	SAME
Product Code	GEX	GEX	SAME
Regulation Name	Laser surgical instrument for use in general and plastic surgery and in dermatology	Laser surgical instrument for use in general and plastic surgery and in dermatology	SAME
Indications for use	The Medical Alexandrite and Nd:YAG laser Therapy System is indicated for the following at the specified wavelength: 755nm Temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime. 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. On all skin types	The SANDRO Dual Laser System is indicated for the following at the specified wavelength: 755nm Temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime. 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. On all skin types (Fitzpatrick I- VI) including tanned	SAME

	(Fitzpatrick I- VI) including tanned skin. Treatment of benign pigmented lesions. Treatment of wrinkles. The photocoagulation of dermatological benign vascular lesions (such as portwine stains, hemangiomas, telangiectasias) 1064nm Removal of unwanted hair, for stable long term or permanent hair reduction. 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. The lasers are indicated on all skin types Fitzpatrick I-VI including tanned skin. Benign pigmented and/or benign vascular lesions, such as, but not limited to port-wine stains, telangiectasia, venus lake, leg veins and spider veins. Benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratosis, nevi, chloasma, skin tags, keratosis. Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. Treatment of wrinkles. Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.)	skin. Treatment of benign pigmented lesions. Treatment of wrinkles. The photocoagulation of dermatological benign vascular lesions (such as portwine stains, hemangiomas, telangiectasias) 1064nm Removal of unwanted hair, for stable long term or permanent hair reduction. 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. The lasers are indicated on all skin types Fitzpatrick I-VI including tanned skin. Benign pigmented and/or benign vascular lesions, such as, but not limited to port-wine stains, telangiectasia, venus lake, leg veins and spider veins. Benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratosis, nevi, chloasma, skin tags, keratosis. Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. Treatment of wrinkles. Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.)	
Laser Type	Alexandrite and Nd:YAG laser	Alexandrite and Nd:YAG laser	SAME
Laser Classification	Class IV	Class IV	SAME
Wavelength	755nm / 1064nm	755nm /1064nm	SAME

Maximum Laser output Energy (J)	755nm:Max. 50J 1064nm:Max. 80J	755nm:Max. 50J 1064nm:Max. 80J	SAME
Spot Size	6/8/10/12/15/18mm	2, 3, 5, 7, 10, 12, 15, 18, 20 mm	Analysis(1)
Pulse Duration	0.7ms-20ms	0.3ms-100ms	Analysis(2)
Frequency	0.5-2Hz	0.5 - 10Hz	Analysis(3)
Aiming Beam	532nm	532nm, 5mW (average)	SAME
Electrical consumption	AC 120V/60Hz, AC 230V/ 50Hz,	220-230V~, 50/60Hz, Single phase	Analysis(4)
Pulse control method	Footswitch	Footswitch	SAME
Skin cooling method	Closed loop water cooling	SCS:Skin Cooling Spray	Analysis(5)
Dimensions (W x L x H)	900*950*425mm	460 mm x 978 mm x 1110 mm	Similar
Weight	135Kg	110 kg	Similar
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with AAMI ES 60601-1, IEC 60601-2-22	SAME
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SAME
Laser Safety	Comply with IEC 60601-2-22, IEC 60825-1	Comply with IEC 60601-2-22, IEC 60825-1	SAME
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	SAME

Analysis：

Analysis(1)

The Spot Size of the proposed device is within the predicate device, and the proposed device has passed the IEC 60601-1 test, IEC 60601-1-2 test, IEC 60601-2-22 test, IEC 60825-1 test. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Analysis(2)

The Pulse Duration of the proposed device is within the predicate device, and the proposed device has passed the IEC 60601-1 test, IEC 60601-1-2 test, IEC 60601-2-22 test, IEC 60825-1 test. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Analysis(3)

The Frequency of the proposed device is within the predicate device, and the proposed device has passed the IEC 60601-1 test, IEC 60601-1-2 test, IEC 60601-2-22 test, IEC 60825-1 test. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Analysis(4)
The Electrical consumption of the proposed device is not exactly the same as the predicate device, in addition to AC 230V/50Hz, the proposed device also supports AC 120V/60Hz power input, the proposed device has passed the IEC 60601-1 test, IEC 60601-1-2 test, IEC 60601-2-22 test, IEC 60825-1 test. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Analysis(5)
The Skin cooling method of the proposed device is closed loop water cooling, this cooling method could ensure the cooling effect, and the proposed device has passed the IEC 60601-1 test, IEC 60601-1-2 test, IEC 60601-2-22 test, IEC 60825-1 test. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

9. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5 Third edition 2009-06-01, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Fourth edition 2021-11, Biological evaluation of medical devices - Part 10: Tests for skin sensitization.
- ISO 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation
- IEC 60601-1 Edition 3.2 2020-08, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-22 Edition 4.0 2019-11, Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification, and requirements

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device SANDRO Dual (K200110).