February 20, 2024

Beijing ADSS Development Co., Ltd.
Song Ying
International Registration Manager
Room 609, F6, Building 13,
Yard 5 Tianhua Street, Daxing District,
Beijing, 102600
China

Re: K231896
Trade/Device Name: Diode Laser Therapy System
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, 2024
Received: January 18, 2024

Dear Song Ying:

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,

Shlomit Halachmi

Shlomit Halachmi -S

Digitally signed by Shlomit Halachmi -S
Date: 2024.02.20 18:39:10 -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)*
K231896

Device Name
Diode Laser Therapy System

Indications for Use *(Describe)*
The Diode Laser Therapy System (Model: FG2000-B/FG2000-B Pro) is indicated for temporary hair reduction.

The Diode Laser Therapy System(Model: FG2000-D+/FG2000-D+Pro/FG2000-E) is indicated for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen. It is suitable for all skin types (Fitzpatrick skin type I-VI), including tanned skin.

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

Submission Number: K231896

1. Submitter's Information

Establishment Registration Information

Beijing ADSS Development Co., Ltd.
Room 609, F6, Building 13, Yard 5 Tianhua Street, Daxing District, Beijing, 102600, P. R. China

Contact Person of applicant
Name: Song Ying
International Registration Manager
TEL: +86 13051615111
Email: irm@adss.com.cn
Summary Preparation date: February 18, 2024

2. Device Information

Trade Name: Diode Laser Therapy System
Model: FG2000-B/FG2000-B Pro/FG2000-D+/FG2000-D+Pro/ FG2000-E
Common name: Powered Laser Surgical Instrument
Regulation Number: 21 CFR 878.4810
Product code: GEX
Regulation Class: Class II
Review panel: General & Plastic Surgery

3. Predicate Device Information

Predicate Device of Diode Laser Therapy System (Model: FG2000-B/FG2000-B Pro)
510(K) Number: K230371
Trade Name: Alma Soprano Titanium
Manufacturer: Alma Lasers Inc.

Predicate Device of Diode Laser Therapy System (Model: FG2000-D+/FG2000-D+Pro/ FG2000-E)
510(K) Number: K220381
Trade Name: Diode Laser Therapy Systems
Manufacturer: Beijing LaserTell Medical Co., Ltd

4. Device description

The Diode Laser Therapy System consists of main unit, handpiece, and its accessories. Diode Laser Therapy System is intended for hair removal, mainly based on the principle of selective photothermal interaction, which means that lasers of specific wavelengths can only be selectively absorbed by the target color base.
The Diode Laser Therapy System(Model: FG2000-B/FG2000-B Pro) are desktop devices, which combines 3 wavelengths (755+808+1064 nm) into a single handpiece to achieve purpose for temporary hair reduction.
The Diode Laser Therapy System (Model: FG2000-D+/FG2000-D+Pro/ FG2000-E) are vertical device, which is a single wavelength (808 nm only) device.

5. Indications for Use

The Diode Laser Therapy System (Model: FG2000-B/FG2000-B Pro) is indicated for temporary hair reduction.

The Diode Laser Therapy System(Model: FG2000-D+/FG2000-D+Pro/FG2000-E) is indicated for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen. It is suitable for all skin types (Fitzpatrick skin type I-VI), including tanned skin.

6. Summary of technological characteristics of device compared to the predicate device

6.1 For Model: FG2000-B/FG2000-B Pro

Item	Subject device	Predicate device (K230371)	Comparison
Device Name	Diode Laser Therapy System	Alma Soprano Titanium	/
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	SE
Class	Class II	Class II	SE
Product Code	GEX	GEX	SE
Indication for use	The Diode Laser Therapy System is indicated for temporary hair reduction. .	The Soprano Titanium diode laser module is intended for use in dermatology procedures requiring coagulation. **The indications for use for the Soprano Trio diode laser module include:**	SE The indication of subject device is covered by the predicate device. The subject

		The Super Hair Removal (SHR) Mode is intended for temporary hair reduction. The Soprano Trio diode laser module HR mode is intended for use in dermatology procedures requiring coagulation. The indications for use for the Soprano Trio diode laser HR module include: Benign vascular and vascular dependent lesions. 810nm Applicator Soprano Titanium 810 nm applicator intended use and indications for use: The indications for use for the 810nm Modified Diode Laser Module 2 cm2 include: The Hair Removal (HR) and Super Hair Removal (SHR) Mode are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen. Use on all skin types (Fitzpatrick I-VI), including tanned skin.(HR, and SHR Modes) 755nm applicator Soprano Titanium 755 nm applicator intended use and indications for use: The indications for use for the 755nm Diode Laser Module include: •The Hair Removal (HR) and Super Hair Removal (SHR) Mode are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen. • Use on all skin types (Fitzpatrick I-VI), including tanned skin.(HR, SHR Modes) NIR Applicator NIR Applicator intended use and indications for use The Alma Lasers NIR Modules intended use is to emit energy in the near infrared (NIR)	device is only intended to use for temporary hair reduction.

		spectrum to provide topical heating. The indications for use for NIR Modules are: • Elevating the tissue temperature for the temporary relief of minor muscle pain and joint pain and stiffness, • The temporary relief of minor joint pain associated with arthritis, • The temporary increase in local circulation where applied, and • The relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.	
Laser Type	Diode laser	Diode laser	SE
Laser Classification	Class IV	Class IV	SE
Laser Wavelength	combination of 755nm/808nm/1064nm	combination of 755nm/810nm/1064nm	SE
Spot size	12×16 mm*mm(1.92cm^2)	20*10 mm*mm (2cm^2);	Different 1.
Pulse width	up to 200ms	Up to 200ms	SE
Energy fluence	2～8J/cm2	2 to 8J/cm2	SE
Pulse frequency	1～10Hz	up to 10 Hz	SE
User interface	LCD Color Touchscreen	LCD Color Touchscreen	SE
Electrical Safety	Comply with ANSI/AAMA ES 60601-1, IEC 60601-2-22	Comply with ANSI/AAMA ES 60601-1, IEC 60601-2-22	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Laser Safety	Comply with IEC 60601-2-22, IEC 60825-1	Comply with IEC 60601-2-22, IEC 60825-1	SE
Handpiece tip material	Quartz crystal	Sapphire	SE
Cytotoxicity	comply with ISO 10993-5:2009	comply with ISO 10993-5:2009	SE
Sensitization	comply with ISO 10993-10:2021	comply with ISO 10993-10:2010	SE
Irritation	comply with ISO 10993-23:2021	comply with ISO 10993-10:2010	SE

6.2 For Model: FG2000-D+/FG2000-D+Pro/FG2000-E

Item	Subject device	Predicate device (K220381)	Comparison
Device Name	Diode Laser Therapy System	Diode Laser Therapy Systems	/
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	SE
Class	Class II	Class II	SE
Product Code	GEX	GEX	SE
Indication for use	The Diode Laser Therapy System is indicated for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen. It is suitable for all skin types (Fitzpatrick skin type I-VI), including tanned skin.	The Diode Laser Therapy Systems 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.	SE
Laser Type	Diode laser	Diode laser	SE
Laser Classification	Class IV	Class IV	SE
Laser Wavelength	808nm	808nm	SE
Spot size	10×10mm*mm	15x15mm*mm;	Different 1
Pulse width	2～100ms	1-300ms	Different 2
Energy fluence	2～100J/cm2	1~100J/cm2	Different 3
Pulse frequency	1～10Hz	1～10Hz	SE
User interface	LCD Color Touchscreen	LCD Color Touchscreen	SE
Electrical Safety	Comply with ANSI/AAMA ES 60601-1, IEC 60601-2-22	Comply with ANSI/AAMA ES 60601-1,, IEC 60601-2-22	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Laser Safety	Comply with IEC 60601-2-22, IEC 60825-1	Comply with IEC 60601-2-22, IEC 60825-1	SE

Handpiece tip materia	Quartz crystal	Sapphire	SE
Cytotoxicity	comply with ISO 10993-5:2009	comply with ISO 10993-5:2009	SE
Sensitization	comply with ISO 10993-10:2021	comply with ISO 10993-10:2010	SE
Irritation	comply with ISO 10993-23: 2021	comply with ISO 10993-10:2010	SE

7. Non-Clinical Tests Performed for Safety and effectiveness

Non clinical tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the subject device complies with the following standards:
IEC60601-1:2005, AMD1:2012, AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012, ES60601-1:2005/AMD2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC /TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
IEC 60601-2-22:2007 + A1:2012 +A2:2019 Medical Electrical Equipment - Part 2: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
IEC 60825-1:2014 (Third Edition) Safety of laser products - Part 1: Equipment classification, and requirements
ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
ISO 10993-10: 2021 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation.

8. Clinical Testing Performed

There was no clinical testing performed.

9. Conclusions

The subject device Diode Laser Therapy System (Model: FG2000-B/FG2000-B Pro) have the similar intended use and similar characteristics as the cleared predicate device. And the bench testing contained in this submission supplied demonstrate that the differences existed do not raise any new questions of safety or effectiveness. Thus, subject device Diode Laser Therapy System is Substantially Equivalent (SE) to the predicate device(Alma Soprano Titanium, K230371).

The subject device Diode Laser Therapy System (Model: FG2000-D+/FG2000-D+Pro/FG2000-E) have the same intended use and similar characteristics as the cleared predicate device. And the bench testing contained in this submission supplied demonstrate that the differences existed do not raise any

new questions of safety or effectiveness. Thus, subject device Diode Laser Therapy System is Substantially Equivalent (SE) to the predicate device (K220381).