July 20, 2022

ShenB Co Ltd
% Connie Hoy
Consultant
Hoy and Associates
1830 Bonnie Way
Sacramento, California 95825

Re: K221363
Trade/Device Name: AF Laser
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: PDZ
Dated: May 10, 2022
Received: May 11, 2022

Dear Connie Hoy:

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,

Jianting Wang
Acting 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)*
K221363

Device Name
AF Laser

Indications for Use *(Describe)*

The AF Laser device is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts 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.

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510K Summary
AF Laser
K221363

This 510(K) Summary of safety and effectiveness for the AF Laser is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	ShenB Co Ltd.
Address:	Shenb Bldg 148 Seongsui-ro Seongdong-Gu, Seoul , KR 04796
Contact Person:	Bora Kim
Contact Information:	kimbora@shenb.com +82-70-4814-2978
Preparation Date:	July 11, 2022
Device Trade Name:	AF Laser - K221363
Common Name:	Lasers For Temporary Increase Of Clear Nail In Patients With Onychomycosis
Regulation Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Number:	21 CFR 878.4810 (Product Code: PDZ)
Legally Marketed Predicate Device:	LunulaLaser (K153164)
Regulatory Class:	Class II Prescription Use
Description of the AF Laser:	The AF Laser is a medical laser used to treat nail fungus (onychomycosis) and promote the growth of healthy nails. The operating mechanism of this device is photochemical reaction that uses two wavelengths -- 635nm and 405nm. The AF laser is a compact, all-in-one device that is intended to be used on the floor and is operated by an intuitive 10.2 inch's wide LCD screen for ease of use. An LCD monitor incorporated into the deck of the device helps the operator check the exact location of treatment area during a procedure.
Intended use of AF Laser:	The AF Laser device is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).

Performance Testing	The following performance data was provided in support of the substantial equivalence determination: IEC 60601-1 Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance IEC 60601-1-2 Test for Medical Equipment for General Requirements for basic safety and essential performance: electromagnetic compatibility IEC 62471:2006 - Photobiological safety of lamps and lamp systems IEC 60825-1:2014 - Safety of laser products - Part 1: Equipment classification and requirements
Clinical Testing	No Clinical testing was conducted as part of this submission.

Substantial Equivalence Discussion

Predicate Device Manufacturer Information

	Proposed device	Predicate Device
Device Name	AF Laser	LunulaLaser (K153164)
Manufacturer	ShenB Co., Ltd 148, Seoungsui-ro Seoungdong-gu Seoul, Korea	Erchonia Corporation 2021 Commerce Drive McKinney, TX 75069

Indications for Use Comparison

Proposed Device – AF Laser	Predicate Device- LunulaLaser	Comparison
The AF Laser device is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).	The LunulaLaser™ device is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.)	Identical

Specification	AF Laser – Proposed Device	LunulaLaser– Predicate Device	Comparison
Laser Wavelength	405nm/635nm (±10%)	405nm/635nm (±10%)	Identical
Output Energy	405nm: 23mW ± 1.85mW 635nm: 17mW ± 1.35mW	405nm: 23.00 ± 2.00mW 635nm: 17.25 ± 1.25mW	Similar
Output area	Line pattern electronically scanned over area of treatment	Line pattern electronically scanned over area of treatment	Identical
Output Type	Constant Wave	Constant Wave	Identical
Operating Time	0-12 minutes (±5%) with 1 minute increment	0-12 minutes	Identical
Dimension	424mm(W) × 308mm(L) × 352mm(H)	300mm(W) x 254mm (L) x 400mm (H)	similar
Weight	17.5kg	10.43 kg	similar
Screen	LCD Touch Screen	LCD Touch screen	Identical

Discussion

The ShenB AF Laser is identical to its predicate device, the Lunula Laser. They share indications for use, laser wavelengths, and the designs of the device treat patient toenails in the same way. The only difference is slightly different sizes and appearance of the device. Therefore, the ShenB AF Laser is substantially equivalent to the Lunula Laser.