July 22, 2024

TerasysD&C Inc.
% Kim Jonghyeon
CEO
GMSC Co., Ltd.
B 612, 66, Cheongcho-ro, Deokyang-gu, Goyang-si
Gyeonggi-do,
Korea, South

Re: K241116
Trade/Device Name: Onycho Laser V
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: April 8, 2024
Received: April 23, 2024

Dear Kim Jonghyeon:

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: 2024.07.22 14:49:18 -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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241116

Device Name
Onycho Laser V

Indications for Use *(Describe)*
The Onycho Laser V 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(1)]

Apr.06, 2024

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer: TerasysD&C. Inc.
- Address: Unit 1101~1108, Building N, 249 Sunhwagung-ro, Namyangju-si, Gyeonggi-do, Republic of Korea

- Contact Name: SangHyeop Han
- Telephone No.: +82 2-2293-6667
- Email Address: qc@terasysdnc.com
- Registration No.: TBD

3. Identification of Proposed Device(s) [21 CFR 807.92(a)(2)]

510(k) Number	K241116
Trade/Device/Model Name	Onycho Laser V
Product Name	Onycho Laser V
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
Classification Product Code	PDZ
Device Class	II
510(k) Review Panel	General and Plastic Surgery

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate device within this submission is shown as follow;

510(k) Number	K221363
Trade/Device/Model Name	AF Laser
Product Name	N/A
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
Classification Product Code	PDZ
Device Class	II
510(k) Review Panel	General and Plastic Surgery

These predicate devices have not been subject to a design-related recall.

5. Description of the Device [21 CFR 807.92(a)(4)]

The 'Onycho Laser V' is a compact device that is positioned on the floor and is operated via a 7.0 inch TFT touch screen for ease of use. The device incorporates lasers and outputs light at two wavelengths, 405 nm and 635 nm, in order to achieve its therapeutic effect.

6. Indications for Use [21 CFR 807.92(a)(5)]

The 'Onycho Laser V' 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.).

7. Technological Comparison [21 CFR 807.92(a)(6)]

Provided below is a table that compares technological characteristics of the Onycho Laser V and the predicate device.

[Table 3. Comparison of Proposed Device to Predicate Devices]

	Proposed Device	Predicate Device	Note
K Number	K241116	K221363	-
Manufacturer	TerasysD&C Inc.	ShenB Co Ltd.	-
Trade Name	Onycho Laser V	AF Laser	-
Product Name	Onycho Laser V	-	-
Product Code	PDZ	PDZ	Identical
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	Identical
510(k) Review Panel	General and Plastic Surgery	General and Plastic Surgery	Identical
Indications for Use	The 'Onycho Laser V' 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 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.).	Identical
Laser Wavelength	405nm/635nm (±10%)	405nm/635nm (±10%)	Identical
Output Energy	405nm: 23mW ± 1.85mW 635nm: 17mW ± 1.35mW	405nm: 23mW ± 1.85mW 635nm: 17mW ± 1.35mW	Identical
Output area	Line pattern electronically scanned over area of treatment	Line pattern electronically scanned over area of treatment	Both devices scan the output beams over the areas being treated.
Output Type	Constant Wave	Constant Wave	Identical
Operating Time	0-12 minutes with 1minute increment	0-12 minutes (±5%) with 1minute increment	Identical
Dimension	530mm(W) × 410 mm(L) ×	424mm(W) × 308mm(L) ×	Similar

	Proposed Device	Predicate Device	Note
	445mm(H)	352mm(H)	
Weight	17kg (1unit)	17.5kg	Similar
Screen	TFT touch 7.0 inch(Diagonal)	LCD Touch Screen	Similar

The Onycho Laser V device uses the same basic laser technology as that used by the predicate device. The technological parameters of the Onycho Laser V device are either identical or similar to those of the predicate device, and the differences do not raise new types of questions regarding the safety and effectiveness for the proposed indications for use

8. Non-Clinical Test Summary

The 'Onycho Laser V conforms to voluntary standards for electrical safety, electromagnetic compatibility, and other performance. Test results from the following performance standards were provided in support of the safety and effectiveness of the Onycho Laser V device

1) The 'Onycho Laser V' conforms to the following performance standards:

Standards No.	Standards Organization	Standard Title	Version	Publication Year
60601-1	IEC	Medical electrical equipment Part 1: General Requirements for basic safety and essential performance	3.2	2020
60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	4.1	2020
60601-2-22	IEC	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	4.0	2019

Standards No.	Standards Organization	Standard Title	Version	Publication Year
60825-1	IEC	Safety of laser products - Part 1: Equipment classification and requirements	3.0	2014

2) Biocompatibility

The 'Onycho Laser V' conforms to the biocompatibility requirements established by the standards.

Standards No.	Standards Organization	Standard Title	Version	Publication Year
10993-5	ISO	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	3.0	2009
10993-10	ISO	Biological evaluation of medical devices - Part 10: Tests for skin sensitization	4.0	2021
10993-23	ISO	Biological evaluation of medical devices - Part 23: Tests for irritation	1.0	2021

3) Software Validation

The software was designed and developed according to a software development process and was verified and validated. Software information is provided in accordance with FDA guidance:

- The content of premarket submissions for software contained in medical devices, on June 14, 2023

9. Conclusion [21 CFR 807.92(b)(3)]

In accordance with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, it is concluded that the 'Onycho Laser V' is substantially equivalent to the predicate device K221363