March 9, 2026

Medicell Healthcare Co.,LTD
% Spencer Walker
Director of Regulatory Affairs
Center For Medical Innovation
350 E. 400 S.
Salt Lake City, Utah 84111

Re: K253960
Trade/Device Name: Medicell Mycosis Laser (MCML24004)
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: December 9, 2025
Received: December 10, 2025

Dear Spencer Walker:

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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2026.03.09 22:35:47 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253960

Please provide the device trade name(s).

Medicell Mycosis Laser (MCML24004)

Please provide your Indications for Use below.

The Medicell Mycosis Laser is indicated for the temporary increase of clear nails in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum, and T. mentagrophytes, and/or yeasts Candida albicans, etc.)

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

K253960

(21 CFR 807.92)

GENERAL INFORMATION

Submitter: Medicell Healthcare, Ltd.

Contact Person: Spencer Walker, MSc.
Center for Medical Innovation || University of Utah
400 South 350 East
Salt Lake City, UT 84111
(801) 708-2238
Spencer.Walker@hsc.utah.edu

Date Prepared: December 9, 2025

Trade Name: Medicell Mycosis Laser (MCML24004)

Common Name: Laser for Clear Nails

Classification Name: Laser for Clear Nails
21 CFR §878.4810, Product Code PDZ

Device Class: Class II

Predicate Device: 510(k) No.: K221363
Model: AF Laser
Manufacture: ShenB Co. Ltd
Classification: PDZ

Device Description:

The Medicell Mycosis Laser is a medical laser used to treat nail fungus (onychomycosis). The device produces two wavelengths of light, 635nm and 405nm, to produce a photochemical reaction to achieve its therapeutic effects. The Mycosis laser is a compact, all-in-one device that is intended to be used on the floor and is operated by an intuitive touch screen for ease of use. An LCD monitor incorporated into the face of the device helps the operator check the exact location of treatment area during a procedure.

Table 1: Medicell Mycosis Laser Model Number

Model No.	Description
MCML24004	Medicell Mycosis Laser

Indications for Use:
The Medicell Mycosis Laser is indicated for use for the temporary increase of clear nails in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum, and T. mentagrophytes, and/ or yeasts Candida albicans, etc.)

Comparative Analysis:
It has been demonstrated that the Medicell Mycosis Laser is comparable to the predicate device in intended use, fundamental scientific technology, design, principles of operation, patient/user interface and functional performance evaluations. The Medicell Mycosis Laser has been fully assessed within the Medicell Risk Management and Design Controls systems. All necessary verification steps met pre-determined acceptance criteria to confirm safety and effectiveness.

It has been demonstrated that the Medicell Mycosis Laser is comparable to the predicate device in the following manner:

- Same Intended Use
- Same Indications for Use
- Same Fundamental Scientific Technology
- Same or similar Operating Principles of Use
- Same Material Properties
- Same or similar Performance Specifications

Table 2: Substantial Equivalence Comparison Chart

	Predicate – K221363 (AF Laser Mycosis Laser)	**Subject Device – (Medicell Mycosis Laser)**	**Comparison**
Ind. for Use	The AF Laser is indicated for use for the temporary increase of clear nails in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum, and T. mentagrophytes, and/or yeasts Candida albicans, etc.)	The Medicell Mycosis Laser is indicated for use for the temporary increase of clear nails in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum, and T. mentagrophytes, and/or yeasts Candida albicans, etc.)	Substantially Equivalent
Classification Name	General Hospital – Laser for Clear Nails 21 CFR §878.4810 Product Code: PDZ Class II	General Hospital – Laser for Clear Nails 21 CFR §878.4810 Product Code: PDZ Class II	Substantially Equivalent
Laser Type	Diode Laser	Diode Laser	Substantially Equivalent
Laser Wavelength	405nm/635nm (±10%)	405nm/635nm (±10%)	Substantially Equivalent

Table 2: Substantial Equivalence Comparison Chart			
	Predicate – K221363 (AF Laser Mycosis Laser)	**Subject Device – (Medicell Mycosis Laser*)***	**Comparison**
Output Power	405nm: 23mW ± 1.85mW 635nm: 17mW ± 1.35mW	405nm: 23mW ± 2.00mW 635nm: 17.25mW ± 1.25mW	Substantially Equivalent
Output Area	Line pattern electronically scanned over area of treatment	Line pattern electronically scanned over area of treatment	Substantially Equivalent
Output Type	Constant Wave	Constant Wave	Substantially Equivalent
Operating Time	0-12 minutes (±5%) with 1 minute increment	12, 15, 20 minutes (±5%) with 1 minute increment	Substantially Equivalent
Dimensions	424mm(W) × 308mm(L) × 352mm(H)	540mm(W) × 304mm(L) × 405mm(H)	Substantially Equivalent
Weight	17.5kg	7.8kg	Substantially Equivalent
Screen	LCD Touch Screen	LCD Touch Screen	Substantially Equivalent
Treatment Bed	Dual Feet Simultaneously	Dual Feet Simultaneously	Substantially Equivalent

Functional/Safety Testing:

The following testing was conducted to validate and verify that the subject device was substantially equivalent to the predicate devices. All data met pre-determined acceptance criteria.

Design Verification – Performance bench testing was conducted to ensure that the Medicell Mycosis Laser met the applicable design and performance requirements throughout its use life, verify conformity to applicable standards, and demonstrate substantial equivalence to the predicate device. The following performance testing was performed or fulfilled with the Medicell Mycosis Laser.

- IEC 60601-1:2020 Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance
- IEC 60601-1-2:2020 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

Table 3: Design Verification and Performance Testing - Summary				
No.	**Test Performed**	**Test Method Applicable Standard**	**Acceptance Criteria**	**Results**
1	Electrical Safety and Essential Performance Testing	IEC60601-1:2020	Device is safe for human use	The subject device meets acceptance criteria
2	Electromagnetic Compatibility (EMC)	IEC60601-1-2:2020	Device is electro magnetically compatible	The subject device meets acceptance criteria
3	Photobiological Safety of Lamps and Lamp Systems	IEC 62471:2008	Device lights are Photobiologically compatible	The subject device meets acceptance criteria
4	Laser Equipment	IEC 60825-1:2014	Blue and Red Laser Equipment Efficiency – Class 3B Laser Diodes	The subject device meets acceptance criteria

Conclusion:
Based on the similarities in design between the subject and predicate devices, and the performance testing performed, the subject Medicell Mycosis Laser is substantially equivalent to the cited predicate device.