

**K253960 Medicell Mycosis Laser (MCML24004)**Mar 9, 2026  
89 days to decisionK253960 · Product code: **PDZ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k253960/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lasers For Temporary Increase Of Clear Nail In Patients With Onychomycosis (PDZ)
Date received	Dec 10, 2025
Decision date	Mar 9, 2026
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medicell Healthcare Co.,LTD</b>
Location	Incheon, KR
Contact	Kangsoo Lim
510(k) history	1 submissions · 1 cleared · 2026-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Center For Medical Innovation</b>
Contact	Spencer Walker

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253960/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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