

**K241116 Onycho Laser V**Jul 22, 2024  
90 days to decisionK241116 · Product code: **PDZ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k241116/>**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	Apr 23, 2024
Decision date	Jul 22, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Terasysd&amp;C, Inc.</b>
Location	Gyeonggi-Do, KR
Contact	Sanghyeop Han
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>GMSC Co., Ltd.</b>
Contact	Kim Jonghyeon

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/k241116/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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