

**K221363 AF Laser**Jul 20, 2022  
70 days to decisionK221363 · Product code: **PDZ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k221363/>**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	May 11, 2022
Decision date	Jul 20, 2022
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>ShenB Co., Ltd.</b>
Location	Seongdong-Gu, KR
Contact	Sunny Kang
510(k) history	11 submissions · 11 cleared · 2020-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hoy and Associates</b>
Contact	Connie Hoy

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/k221363/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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