FDA 510(k) Premarket Notification

K221363 AF Laser

CLEARED

Jul 20, 2022
70 days to decision

K221363 · Product code: **PDZ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221363/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Hoy and Associates**
Contact	Connie Hoy

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