

**K113810 MODIFIED ALMA LASERS HARMONY 1064NM
(ND:YAG) MODULES**Mar 8, 2012
76 days to decisionK113810 · Product code: **PDZ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k113810/>**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	Dec 23, 2011
Decision date	Mar 8, 2012
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alma Lasers, Inc.
Location	Buffalo Grove, IL, US
Contact	TATIANA EPSTEIN
510(k) history	19 submissions · 19 cleared · 2010-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113810/>, Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026