

K103338 COOLTOUCHNov 1, 2011
351 days to decisionK103338 · Product code: **PDZ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k103338/>**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	Nov 15, 2010
Decision date	Nov 1, 2011
Days to decision	351 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	New Star Lasers, Inc.
Location	Auburn, CA, US
Contact	NATALIE R VOLLRATH
510(k) history	29 submissions · 29 cleared · 1995-2014

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