

K120938 THE PL-1064 LASER SYSTEMSep 24, 2012
186 days to decisionK120938 · Product code: **PDZ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k120938/>**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	Mar 22, 2012
Decision date	Sep 24, 2012
Days to decision	186 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sheumann Laser, Inc.
Location	Oviedo, FL, US
Contact	TIMOTHY J SHEA
510(k) history	2 submissions · 2 cleared · 2012-2015

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