

K153164 LunulaLaserJun 3, 2016
214 days to decisionK153164 · Product code: **PDZ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k153164/>**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 2, 2015
Decision date	Jun 3, 2016
Days to decision	214 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Erchonia Medical, Inc.
Location	Littleton, CO, US
Contact	STEVE SHANKS
510(k) history	10 submissions · 10 cleared · 2004-2016

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