FDA 510(k) Premarket Notification

K190034 REMY Medical Therapy Laser System

CLEARED

May 15, 2019
128 days to decision

K190034 · Product code: **PDZ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k190034/

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	Jan 7, 2019
Decision date	May 15, 2019
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Footdocprenur, LLC**
Location	Cherry Hill, NJ, US
Contact	David Zuckerman
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Braunsolutions**
Contact	Alexander Braun Henderson

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