FDA 510(k) Premarket Notification

K211265 TFX-LT2000 Therapy Light

CLEARED

Nov 17, 2022
570 days to decision

K211265 · Product code: **PDZ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k211265/

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	Apr 26, 2021
Decision date	Nov 17, 2022
Days to decision	570 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Toefx, Inc.**
Location	Hamilton, CA
Contact	Monika Yazdanian
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Braunsolutions Regulatory Group**
Contact	Alexander Braun Henderson

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