FDA 510(k) Premarket Notification

K213332 Multifrax Laser System

CLEARED

Jun 3, 2022
240 days to decision

K213332 · Product code: **ONG** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k213332/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument With Microbeamfractional Output (ONG)
Date received	Oct 6, 2021
Decision date	Jun 3, 2022
Days to decision	240 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Paradigm Medical Corporation**
Location	San Diego, CA, US
Contact	Nikolai Tankovich
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**O'Connell Regulatory Consultants, Inc.**
Contact	Maureen O'Connell

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