FDA 510(k) Premarket Notification

K241547 Diode Laser Therapy Device (DF-DIODE LASER-S1)

CLEARED

Aug 13, 2024
74 days to decision

K241547 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k241547/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 31, 2024
Decision date	Aug 13, 2024
Days to decision	74 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Weifang Dragonfly Electronics Technology Co., Ltd.**
Location	Weifang, CN
Contact	Ray Zhao
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Beijing Believe-Med Technology Service Co., Ltd.**
Contact	Ray Wang

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