FDA 510(k) Premarket Notification

K212733 Diode laser therapy device

CLEARED

Jun 6, 2023
645 days to decision

K212733 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k212733/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 30, 2021
Decision date	Jun 6, 2023
Days to decision	645 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beijing Star New Tech Co., Ltd.**
Location	Beijing, CN
Contact	Liang ZhongDong
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Shanghai Truthful Information Technology Co., Ltd.**
Contact	Boyle Wang

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