FDA 510(k) Premarket Notification

K212478 Dermatological diode laser system

CLEARED

Jan 14, 2022
158 days to decision

K212478 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k212478/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 9, 2021
Decision date	Jan 14, 2022
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beijing Stelle Laser Technology Co., Ltd.**
Location	Beijing, CN
Contact	Zhao Changcheng
510(k) history	1 submissions · 1 cleared · 2022-2022

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