FDA 510(k) Premarket Notification

K220381 Diode Laser Therapy Systems

CLEARED

May 20, 2022
99 days to decision

K220381 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k220381/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 10, 2022
Decision date	May 20, 2022
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beijing Lasertell Medical Co., Ltd.**
Location	Beijing, CN
Contact	Zeng Xun
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