FDA 510(k) Premarket Notification

CLEARED

K210168 Diode Laser Therapy Systems

May 10, 2021
108 days to decision

K210168 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k210168/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 22, 2021
Decision date	May 10, 2021
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beijing Kes Biology Technology Co., Ltd.**
Location	Shanghai, CN
Contact	Wei Meng Meng
510(k) history	3 submissions · 3 cleared · 2013-2021

REGULATORY CONSULTANT

Consulting firm	**Mid-Link Consulting Co, Ltd.**
Contact	Diana Hong

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