FDA 510(k) Premarket Notification

K221312 Diode Laser Hair Removal Device

CLEARED

Jun 29, 2022
55 days to decision

K221312 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221312/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 5, 2022
Decision date	Jun 29, 2022
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Guangzhou Chuang Zao Mei Technology Co., Ltd.**
Location	Guangzhou, CN
Contact	Karpov Aleksandr
510(k) history	2 submissions · 2 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	**Askway Innovative , Ltd.**
Contact	Asher No last name provided

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