FDA 510(k) Premarket Notification

K202257 Dermatological Diode Laser Systems

CLEARED

Apr 23, 2021
256 days to decision

K202257 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k202257/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 10, 2020
Decision date	Apr 23, 2021
Days to decision	256 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zhuolu Jontelaser Manufacturing Technology Co., Ltd.**
Location	Zhangjiakou, CN
Contact	Karen Liu
510(k) history	2 submissions · 2 cleared · 2020-2021

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