FDA 510(k) Premarket Notification

K202601 Single-use Sterile medical laser fiber

CLEARED

Dec 15, 2020
98 days to decision

K202601 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k202601/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 8, 2020
Decision date	Dec 15, 2020
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Realton (Suzhou) Medical Technology Co., Ltd.**
Location	Suzhou, CN
Contact	Mingzhu Liu
510(k) history	3 submissions · 3 cleared · 2020-2021

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k202601/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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