FDA 510(k) Premarket Notification

CLEARED

K202702 FLARE Single-Use Surgical Laser Fiber

Feb 26, 2021
163 days to decision

K202702 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k202702/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 16, 2020
Decision date	Feb 26, 2021
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	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

REGULATORY CONSULTANT

Consulting firm	**Guangzhou Osmunda Medical Device Technical Service Co., Ltd.**
Contact	Olivia Meng

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k202702/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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