FDA 510(k) Premarket Notification

K203255 4K UHD Laparoscope

CLEARED

Feb 24, 2021
112 days to decision

K203255 · Product code: **GCJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k203255/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Nov 4, 2020
Decision date	Feb 24, 2021
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Scivita Medical Technology Co., Ltd.**
Location	Suzhou, CN
Contact	Ruqin Wu
510(k) history	12 submissions · 12 cleared · 2019-2026

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