FDA 510(k) Premarket Notification

K212950 FUJIFILM Video Laparoscope EL-R740M30

CLEARED

Dec 2, 2021
77 days to decision

K212950 · Product code: **GCJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k212950/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Sep 16, 2021
Decision date	Dec 2, 2021
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fujifilm Corporaton**
Location	Tokyo, JP
Contact	Randy Vader
510(k) history	6 submissions · 6 cleared · 2020-2023

REGULATORY CONSULTANT

Consulting firm	**Fujifilm Medical Systems U.S.A, Inc.**
Contact	Dhara Buch

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