FDA 510(k) Premarket Notification

K202130 FUJIFILM Video Laparoscope

CLEARED

Aug 20, 2020
20 days to decision

K202130 · Product code: **GCJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k202130/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jul 31, 2020
Decision date	Aug 20, 2020
Days to decision	20 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fujifilm Corporation**
Location	Ashigara Kami-Gun, JP
Contact	Randy Vader
510(k) history	63 submissions · 63 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	**Fujifilm Medical Systems U.S.A, Inc.**
Contact	Kamila Sak

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