FDA 510(k) Premarket Notification

K221551 FUJIFILM Endoscope Model EI-740D/S

CLEARED

Jan 27, 2023
241 days to decision

K221551 · Product code: **FDS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k221551/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	May 31, 2022
Decision date	Jan 27, 2023
Days to decision	241 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 Healthcare Americas Corporation**
Contact	Kotei Aoki

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