FDA 510(k) Premarket Notification

CLEARED

K221238 FUJIFILM Ultrasonic Endoscope EG-740UT

Aug 19, 2022
112 days to decision

K221238 · Product code: **ODG** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k221238/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Apr 29, 2022
Decision date	Aug 19, 2022
Days to decision	112 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	62 submissions · 62 cleared · 2018-2026

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