FDA 510(k) Premarket Notification

K240142 FUJIFILM Endoscope Model EG-840N

CLEARED

Sep 4, 2024
230 days to decision

K240142 · Product code: **FDS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k240142/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Jan 18, 2024
Decision date	Sep 4, 2024
Days to decision	230 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	FUJIFILM Endoscope Model EG-840T; FUJIFILM Endoscope Model EG-840TP

APPLICANT

Company	**Fujifilm Corporation**
Location	Ashigara Kami-Gun, JP
Contact	Chaitrali Kulkarni
510(k) history	62 submissions · 62 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	**FUJIFILM Healthcare Americas Corporation**
Contact	Chaitrali Kulkarni

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