

**K243261 FUJIFILM Endoscope Model EC-860P/M**May 23, 2025  
220 days to decisionK243261 · Product code: **FDF** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k243261/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Oct 15, 2024
Decision date	May 23, 2025
Days to decision	220 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	FUJIFILM Endoscope Model EC-860P/L; FUJIFILM Endoscope Model EC-860S/L

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>FUJIFILM Healthcare Americas Corporation</b>
Contact	Chaitrali Kulkarni

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

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