

**K243260 FUJIFILM Processor EP-8000**Apr 11, 2025  
178 days to decisionK243260 · Product code: **FET** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k243260/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Video Imaging System/component, Gastroenterology-urology (FET)
Date received	Oct 15, 2024
Decision date	Apr 11, 2025
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	FUJIFILM Endoscope Model EG-860R

**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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