

K251861 FUJIFILM Endoscope Model ED-S100TPMar 9, 2026
265 days to decisionK251861 · Product code: **FDT** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k251861/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Duodenoscope And Accessories, Flexible/rigid (FDT)
Date received	Jun 17, 2025
Decision date	Mar 9, 2026
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	FUJIFILM Endoscope Model ED-S100XP; FUJIFILM Processor Model VS-1000

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](https://accessdata.fda.gov)

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