

K250900 EvoEndo Single-Use Endoscopy SystemJun 16, 2025
83 days to decisionK250900 · Product code: **FDS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k250900/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Mar 25, 2025
Decision date	Jun 16, 2025
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	EvoEndo, Inc.
Location	Centennial, CO, US
Contact	Paul Imaoka
510(k) history	4 submissions · 4 cleared · 2022-2026

REGULATORY CONSULTANT

Consulting firm	AlvaMed, Inc.
Contact	Keira Jessop

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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