

K260573 EvoEndo Single-Use Endoscopy SystemApr 21, 2026
60 days to decisionK260573 · Product code: **FDS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k260573/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Feb 20, 2026
Decision date	Apr 21, 2026
Days to decision	60 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)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260573/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026