FDA 510(k) Premarket Notification

K260573 EvoEndo Single-Use Endoscopy System

CLEARED

Apr 21, 2026
60 days to decision

K260573 · Product code: **FDS** · Gastroenterology & Urology
Source: 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