FDA 510(k) Premarket Notification

CLEARED

K251708 EvoEndo Single-Use Endoscopy System

Oct 10, 2025
129 days to decision

K251708 · Product code: **FDS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k251708/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Jun 3, 2025
Decision date	Oct 10, 2025
Days to decision	129 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k251708/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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