FDA 510(k) Premarket Notification

K260314 Ancora-SB

CLEARED

May 1, 2026
91 days to decision

K260314 · Product code: **FDA** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k260314/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enteroscope And Accessories (FDA)
Date received	Jan 30, 2026
Decision date	May 1, 2026
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aspero Medical, Inc.**
Location	Fort Collins, CO, US
Contact	Mark Rentschler
Website	https://asperomedical.com
510(k) history	2 submissions · 2 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	**Nancy Sauer Regulatory Consulting, LLC**
Contact	Nancy Sauer

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov