

K231323 Ancora-SBAug 31, 2023
115 days to decisionK231323 · Product code: **FDA** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k231323/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enteroscope And Accessories (FDA)
Date received	May 8, 2023
Decision date	Aug 31, 2023
Days to decision	115 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	RQM+
Contact	Pierre Bounaud

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/k231323/> 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 25, 2026