FDA 510(k) Premarket Notification

K231323 Ancora-SB

CLEARED

Aug 31, 2023
115 days to decision

K231323 · 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