

K242668 Gastro Concepts Air AssistDec 13, 2024
99 days to decisionK242668 · Product code: **FER** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k242668/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anoscope And Accessories (FER)
Date received	Sep 5, 2024
Decision date	Dec 13, 2024
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gastro Concepts, LLC
Location	Wilmington, DE, US
Contact	Rick Brown
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Prime Path Medtech
Contact	Sarah Moss

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

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