

**K252605 mcompass Anorectal Balloon Expulsion Catheter  
(RMD-003-001)**Dec 5, 2025  
109 days to decisionK252605 · Product code: **FFX** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k252605/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Aug 18, 2025
Decision date	Dec 5, 2025
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medspira, LLC</b>
Location	Minneapolis, MN, US
Contact	Evan Johnston
510(k) history	3 submissions · 3 cleared · 2012-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Bluebird Consulting, LLC</b>
Contact	Melinda Swanson

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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