FDA 510(k) Premarket Notification

CLEARED

K252605 mcompass Anorectal Balloon Expulsion Catheter (RMD-003-001)

Dec 5, 2025
109 days to decision

K252605 · Product code: **FFX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k252605/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Bluebird Consulting, LLC**
Contact	Melinda Swanson

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