

**K160287 Rapid Barostat Bag (RBB) Pump and Catheter**Mar 14, 2017  
405 days to decisionK160287 · Product code: **FFX** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k160287/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Feb 3, 2016
Decision date	Mar 14, 2017
Days to decision	405 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mui Scientific</b>
Location	Mississauga, Ontario, CA
Contact	TAMMY MUI
510(k) history	4 submissions · 4 cleared · 1983-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160287/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 1, 2026