

**K160170 Lehman Manometry Catheter**Jun 20, 2016  
145 days to decisionK160170 · Product code: **FFX** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k160170/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Jan 27, 2016
Decision date	Jun 20, 2016
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wilson-Cook Medical, Inc.</b>
Location	Winstrom-Salem, NC, US
Contact	Doris A. Hawks
510(k) history	124 submissions · 117 cleared · 1985-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160170/> 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 2, 2026