

**K181317 Fusion Cytology Brush, CytoMax II Double Lumen Cytology Brush**Feb 8, 2019  
266 days to decisionK181317 · Product code: **FDX** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k181317/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Cytology Brush (FDX)
Date received	May 18, 2018
Decision date	Feb 8, 2019
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wilson-Cook Medical, Inc.</b>
Location	Winstrom-Salem, NC, US
Contact	Sierra Lowe
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/k181317/>. 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 May 31, 2026