

**K153763 Howell Biliary Aspiration Needle**Apr 6, 2017  
463 days to decisionK153763 · Product code: **FCK** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k153763/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy, Suction (FCK)
Date received	Dec 30, 2015
Decision date	Apr 6, 2017
Days to decision	463 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	Jennifer McMahan
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/k153763/> 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