

**K193344 Tri-Ex Extraction Balloon with Multiple Sizing**Dec 13, 2019  
10 days to decisionK193344 · Product code: **GCA** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k193344/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Biliary Catheter For Stone Removal That May Also Allow For Irrigation And Contrast Injection (GCA)
Date received	Dec 3, 2019
Decision date	Dec 13, 2019
Days to decision	10 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	Theresa de Prat
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/k193344/> 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