

K200247 Fusion Quattro Extraction BalloonFeb 27, 2020
27 days to decisionK200247 · Product code: **GCA** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k200247/>**SUBMISSION DETAILS**

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	Jan 31, 2020
Decision date	Feb 27, 2020
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wilson-Cook Medical, Inc.
Location	Winstrom-Salem, NC, US
Contact	Tiffany A Thomas
510(k) history	124 submissions · 117 cleared · 1985-2025

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