

**K171548 Cotton Graduated Dilation Catheter, Fusion Biliary Dilation Catheter, Soehendra Biliary Dilation Catheter, Geenen Graduated Dilation Catheter**Oct 13, 2017  
140 days to decisionK171548 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k171548/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	May 26, 2017
Decision date	Oct 13, 2017
Days to decision	140 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	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/k171548/>; 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