

K171223 Quantum TTC Biliary Balloon DilatorJun 16, 2017
51 days to decisionK171223 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k171223/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Apr 26, 2017
Decision date	Jun 16, 2017
Days to decision	51 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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