

K101095 DIRECT PERORAL CHOLANGIOSCOPY BALLOONJul 19, 2010
90 days to decisionK101095 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k101095/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Apr 20, 2010
Decision date	Jul 19, 2010
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wilson-Cook Medical, Inc.
Location	Winstrom-Salem, NC, US
Contact	SCOTTIE FARIOLE
510(k) history	125 submissions · 118 cleared · 1985-2026

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