

K170740 GORE VIABIL Short Wire Biliary EndoprosthesisMay 8, 2017
59 days to decisionK170740 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k170740/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Mar 10, 2017
Decision date	May 8, 2017
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	W.L. Gore & Associates, Inc.
Location	Mchenry, IL, US
Contact	Barbara L. Smith
Website	http://www.gore.com/
510(k) history	163 submissions · 148 cleared · 1980-2025

W.L. Gore & Associates, Inc. is a global materials science company specializing in advanced medical devices. The company operates with a manufacturing facility in McHenry, US. The company has received FDA 510(k) clearances from total submissions since its first clearance in 1980. Cardiovascular devices represent a dominant category, including vascular grafts and balloon catheters. Recent clearances also span general surgery, plastic surgery, and gastroenterology applications. The latest FDA 510(k) clearance in 2025 reflects ongoing regulatory activity. W.L. Gore & Associa...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170740/> Data sourced from FDA 510(k) public records (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. - Generated May 19, 2026