

**K041423 VIABIL BILIARY ENDOPROSTHESIS**Jul 21, 2004  
54 days to decisionK041423 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k041423/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	May 28, 2004
Decision date	Jul 21, 2004
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>W.L. Gore &amp; Associates, Inc.</b>
Location	Mchenry, IL, US
Contact	Michael Ivey
Website	<a href="http://www.gore.com/">http://www.gore.com/</a>
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...

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