

**K050534 XPERT SELF-EXPANDING TRANSHEPATIC BILIARY STENT SYSTEM**May 20, 2005  
79 days to decisionK050534 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k050534/>**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	Mar 2, 2005
Decision date	May 20, 2005
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Abbott Laboratories</b>
Location	Abbott Park, IL, US
Contact	Joanna Develter
Website	<a href="http://www.abbott.com">http://www.abbott.com</a>
510(k) history	883 submissions · 868 cleared · 1976-2026

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k050534/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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