

**K063481 MODIFICATION TO RX HERCULINK ELITE BILIARY STENT SYSTEM**Sep 14, 2007  
301 days to decisionK063481 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k063481/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Nov 17, 2006
Decision date	Sep 14, 2007
Days to decision	301 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Abbott Vascular, Inc.</b>
Location	Redwood, CA, US
Contact	NADINE SMITH
510(k) history	20 submissions · 17 cleared · 2000-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k063481/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026