

**K061566 PRIMUS GPS BILIARY STENT SYSTEM**Aug 31, 2006  
86 days to decisionK061566 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k061566/>**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	Jun 6, 2006
Decision date	Aug 31, 2006
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ev3, Inc.</b>
Location	Plymouth, MN, US
Contact	MELISSA SOMMERFELD
510(k) history	35 submissions · 26 cleared · 2003-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061566/> 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 June 6, 2026