

**K050725 PROTEGE GPS SELF-EXPANDING NITINOL STENT**Apr 20, 2005  
30 days to decisionK050725 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k050725/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Mar 21, 2005
Decision date	Apr 20, 2005
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ev3 Corporation</b>
Location	Plymouth, MN, US
Contact	GLEN D SMYTHE
510(k) history	5 submissions · 4 cleared · 2003-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050725/> 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 30, 2026