

**K042204 MODIFICATION TO PROTEGE GPS SELF-EXPANDING
NITINOL STENT**Aug 23, 2004
7 days to decisionK042204 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k042204/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Aug 16, 2004
Decision date	Aug 23, 2004
Days to decision	7 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ev3, Inc.
Location	Plymouth, MN, US
Contact	GLEN D SMYTHE
510(k) history	35 submissions · 26 cleared · 2003-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042204/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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