

K043243 PRIMUS STENT AND DELIVERY SYSTEMDec 9, 2004
16 days to decisionK043243 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k043243/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Nov 23, 2004
Decision date	Dec 9, 2004
Days to decision	16 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

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