

K053459 OMNILINK .035 BILIARY STENT SYSTEMApr 12, 2006
120 days to decisionK053459 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k053459/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 13, 2005
Decision date	Apr 12, 2006
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Guidant Corporation
Location	St. Paul, MN, US
Contact	SYLVIA HERNANDEZ
510(k) history	15 submissions · 12 cleared · 2003-2006

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