

K053454 RX HERCULINK ELITE BILIARY STENT SYSTEMMar 6, 2006
87 days to decisionK053454 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k053454/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 9, 2005
Decision date	Mar 6, 2006
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053454/> Data sourced from FDA 510(k) public records (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. - Generated June 30, 2026