

K014184 MODIFICATION TO DYNALINK .035 BILIARY SELF-EXPANDING STENT SYSTEMJan 18, 2002
29 days to decisionK014184 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k014184/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 20, 2001
Decision date	Jan 18, 2002
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Guidant Corp.
Location	Santa Clara, CA, US
Contact	SABA MODJARRAD
510(k) history	71 submissions · 56 cleared · 1997-2006

Guidant Corp. is a medical device manufacturer specializing in cardiovascular devices and surgical products. Headquartered in Indianapolis, Indiana, the company designs and manufactures artificial cardiac pacemakers, implantable cardioverter-defibrillators, stents, and related cardiovascular medical products. Guidant received FDA 510(k) clearances from total submissions between 1997 and 2006. The company's regulatory portfolio is dominated by cardiovascular devices, including guide wires, embolic protection systems, stents, and hemostasis valves. The company also cleared ...

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