

**K014007 DYNALINK .018 BILLARY SELF-EXPANDING STENT SYSTEM**Jan 7, 2002  
33 days to decisionK014007 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k014007/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 5, 2001
Decision date	Jan 7, 2002
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Guidant Corp.</b>
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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