

**K011881 DYNALINK .035 BILIARY SELF-EXPANDING STENT SYSTEM**Jul 18, 2001  
30 days to decisionK011881 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k011881/>**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	Jun 18, 2001
Decision date	Jul 18, 2001
Days to decision	30 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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