

**K002143 DYNALINK BILIARY SELF-EXPANDING STENT SYSTEM**Oct 12, 2000  
87 days to decisionK002143 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k002143/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jul 17, 2000
Decision date	Oct 12, 2000
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Guidant Corp.</b>
Location	Santa Clara, CA, US
Contact	SUSAN SILAVIN, PH.D.
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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Device record: <https://www.510kdatabase.net/k002143/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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