

**K992319 RX MEGALINK SDS BILIARY STENT SYSTEM, OTW  
MEGALINK SDS BILIARY STENT SYSTEM**Oct 8, 1999  
88 days to decisionK992319 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k992319/>**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 12, 1999
Decision date	Oct 8, 1999
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Guidant Corp.</b>
Location	Santa Clara, CA, US
Contact	SANDRA SUNDELL
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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