

K011039 OMNILINK .018 BILIARY STENT SYSTEMMay 8, 2001
33 days to decisionK011039 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k011039/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Apr 5, 2001
Decision date	May 8, 2001
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Guidant Corp.
Location	Santa Clara, CA, US
Contact	CURTIS TRUESDALE
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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