

**K001222 OTW MEGALINK SDS BILLIARY STENT SYSTEM,
MODELS 1005509-18, 1005510-18, 1005511-18, 1005512-18,
1005509-28, 1005510-28, 1**May 17, 2000
30 days to decisionK001222 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k001222/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Apr 17, 2000
Decision date	May 17, 2000
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Guidant Corp.
Location	Santa Clara, CA, US
Contact	MARGARET ANDERSON
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 ...