

**K032530 MODIFICATION TO OMNILINK .035 BILIARY STENT SYSTEM**

Oct 23, 2003  
69 days to decision

K032530 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k032530/>

**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	Aug 15, 2003
Decision date	Oct 23, 2003
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Guidant Corporation</b>
Location	St. Paul, MN, US
Contact	MICHELLE GROSSMAN
510(k) history	15 submissions · 12 cleared · 2003-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k032530/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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