FDA 510(k) Premarket Notification

K032530 MODIFICATION TO OMNILINK .035 BILIARY STENT SYSTEM

CLEARED

Oct 23, 2003
69 days to decision

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

SUBMISSION DETAILS

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

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