FDA 510(k) Premarket Notification

K033834 OMNILINK .018 BILIARY STENT SYSTEM

CLEARED

Jan 2, 2004
23 days to decision

K033834 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k033834/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 10, 2003
Decision date	Jan 2, 2004
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Guidant Corp.**
Location	Santa Clara, CA, US
Contact	MICHELLE GROSSMAN
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 ...