FDA 510(k) Premarket Notification

CLEARED

K983075 GUIDANT MEGALINK BILIARY STENT, MODEL #'S 1002949-18, 1002949-28, 1002949-38

Mar 3, 1999
182 days to decision

K983075 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k983075/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Sep 2, 1998
Decision date	Mar 3, 1999
Days to decision	182 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Guidant Corp.**
Location	Santa Clara, CA, US
Contact	SANDRA SUNDELL
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 ...