FDA 510(k) Premarket Notification

K992863 LEAD STYLET,MODELS 6505,6506,6507,6508

CLEARED

Nov 12, 1999
79 days to decision

K992863 · Product code: **DRB** · Cardiovascular
Source: https://www.510kdatabase.net/k992863/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stylet, Catheter (DRB)
Date received	Aug 25, 1999
Decision date	Nov 12, 1999
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Guidant Corp.**
Location	Santa Clara, CA, US
Contact	SHERYL POGANSKI
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 ...