FDA 510(k) Premarket Notification

CLEARED

K042218 ACCUNET EMBOLIC PROTECTION SYSTEM, RX ACCUNET EMBOLIC PROTECTION SYSTEM

Aug 31, 2004
26 days to decision

K042218 · Product code: **NTE** · Cardiovascular
Source: https://www.510kdatabase.net/k042218/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Temporary Carotid Catheter For Embolic Capture (NTE)
Date received	Aug 5, 2004
Decision date	Aug 31, 2004
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Guidant Corp.**
Location	Santa Clara, CA, US
Contact	LARAINE PANGELINA
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 ...