FDA 510(k) Premarket Notification

K021455 RAPIDO GUIDING CATHETER, 6F MODEL# 6776

CLEARED

Aug 2, 2002
88 days to decision

K021455 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k021455/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	May 6, 2002
Decision date	Aug 2, 2002
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary
Other names	RAPIDO GUIDING CATHETER, 8F MODEL# 6775, 6777, 6778, 6779, 6780, 6781, 6782,

APPLICANT

Company	**Guidant Corp.**
Location	Santa Clara, CA, US
Contact	KAREN S ALSOP
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 ...