FDA 510(k) Premarket Notification

K012002 VIKING OPTIMA GUIDING CATHETER

CLEARED

Jul 26, 2001
29 days to decision

K012002 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k012002/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Jun 27, 2001
Decision date	Jul 26, 2001
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Guidant Corp.**
Location	Santa Clara, CA, US
Contact	STACEY SIMON
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 ...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k012002/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 30, 2026