

**K981381 ACS HI-TORQUE CROSS-IT GUIDE WIRE WITH
HYDROCOAT HYDROPHILIC COATING PRODUCT FAMILY
MODELS 1003211H,1003212HJ,1003213H,1**Jul 15, 1998
90 days to decisionK981381 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k981381/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Apr 16, 1998
Decision date	Jul 15, 1998
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Guidant Corp.
Location	Santa Clara, CA, US
Contact	MARGARET ANDERSON
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 ...