

**K031678 HI-TORQUE BALANCE INIVERSAL GUIDE WIRE WITH
HYDROCOAT HYDROPHILIC COATING**Aug 26, 2003
88 days to decisionK031678 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k031678/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	May 30, 2003
Decision date	Aug 26, 2003
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Guidant Corp.
Location	Santa Clara, CA, US
Contact	BRUCE CERWIN
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 ...

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