

**K020340 MODIFICATION TO HI-TORQUE WHISPER LS AND MS
GUIDE WIRES WITH HYDROCOAT HYDROPHILIC COATING**Mar 1, 2002
28 days to decisionK020340 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k020340/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Feb 1, 2002
Decision date	Mar 1, 2002
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Guidant Corp.
Location	Santa Clara, CA, US
Contact	JENNIFER PAE RIGGS
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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