

**K971815 ASC BALANCE MIDDLEWEIGHT GUIDE WIRE**Jul 9, 1997  
54 days to decisionK971815 · Product code: **DQX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k971815/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	May 16, 1997
Decision date	Jul 9, 1997
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Guidant Corp.</b>
Location	Santa Clara, CA, US
Contact	MONA MIRAPURI
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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