

K983033 ACS HT BALANCE MIDDLEWEIGHT GUIDE WIRENov 10, 1998
71 days to decisionK983033 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k983033/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Aug 31, 1998
Decision date	Nov 10, 1998
Days to decision	71 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 ...