

**K021228 HI-TORQUE BALANCE, BALANCE MIDDLEWEIGHT,
BALANCE HEAVYWEIGHT, BALANCE TREK AND THE
BALANCE MIDDLEWEIGHT UNIVERSAL GUIDE**May 15, 2002
27 days to decisionK021228 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k021228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Apr 18, 2002
Decision date	May 15, 2002
Days to decision	27 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 ...