FDA 510(k) Premarket Notification

CLEARED

K061453 HI-TORQUE WHISPER VIEW GUIDE WIRE

Jun 22, 2006
28 days to decision

K061453 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k061453/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	May 25, 2006
Decision date	Jun 22, 2006
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Guidant Corp.**
Location	Santa Clara, CA, US
Contact	KATHLEEN VITTUM
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 ...