FDA 510(k) Premarket Notification

K023300 HI-TORQUE WHISPER LS

CLEARED

Oct 28, 2002
25 days to decision

K023300 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k023300/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Oct 3, 2002
Decision date	Oct 28, 2002
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary
Other names	HI-TORQUE WHISPER MS; HI-TORQUE WHISPER MS CS-J; HI-TORQUE WHISPER ES; HI-TORQUE WHISPER ES CS-J

APPLICANT

Company	**Guidant Corp.**
Location	Santa Clara, CA, US
Contact	JANELL A COLLEY
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 ...