FDA 510(k) Premarket Notification

CLEARED

K991102 COPILOT BLEEDBACK CONTROL VALVE, MODEL 1003331

Jun 9, 1999
69 days to decision

K991102 · Product code: **DTL** · Cardiovascular
Source: https://www.510kdatabase.net/k991102/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (DTL)
Date received	Apr 1, 1999
Decision date	Jun 9, 1999
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Guidant Corp.**
Location	Santa Clara, CA, US
Contact	STACEY SIMON
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 ...