

**K012763 SORIN BIOMEDICA SMART BCD
VANGUARD,SURFACE MODIFIED BLOOD CARDIOPLEGIA
SYSTEM**Nov 15, 2001
90 days to decisionK012763 · Product code: **DRT** · Cardiovascular
Source: <https://www.510kdatabase.net/k012763/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Aug 17, 2001
Decision date	Nov 15, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cobe Cardiovascular, Inc.
Location	Arvada, CO, US
Contact	LYNNE LEONARD
510(k) history	43 submissions · 43 cleared · 1992-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012763/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026