

**K021830 SORIN BIOMEDICA SMARXT BCD VANGUARD
SURFACE MODIFIED CARDIOPLEGIA SYSTEM**Jul 2, 2002
28 days to decisionK021830 · Product code: DTR · Cardiovascular
Source: <https://www.510kdatabase.net/k021830/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Jun 4, 2002
Decision date	Jul 2, 2002
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k021830/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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