

**K993001 COBE SMARXT HVR 4000 SURFACE MODIFIED
HARDSHELL VENOUS RESERVOIR, FILTERED &
NONFILTERED**Dec 3, 1999
87 days to decisionK993001 · Product code: **DTN** · Cardiovascular
Source: <https://www.510kdatabase.net/k993001/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Sep 7, 1999
Decision date	Dec 3, 1999
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k993001/>. 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