FDA 510(k) Premarket Notification

CLEARED

K993001 COBE SMARXT HVR 4000 SURFACE MODIFIED HARDSHELL VENOUS RESERVOIR, FILTERED & NONFILTERED

Dec 3, 1999
87 days to decision

K993001 · 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