FDA 510(k) Premarket Notification

K991452 COBE OPTIMIN HOLLOW FIBER MEMBRANE OXYGENATOR

CLEARED

Oct 7, 1999
164 days to decision

K991452 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k991452/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Apr 26, 1999
Decision date	Oct 7, 1999
Days to decision	164 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