FDA 510(k) Premarket Notification

K974085 COBE OXYGENATOR PRODUCTS

CLEARED

Jan 27, 1998
90 days to decision

K974085 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k974085/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Oct 29, 1997
Decision date	Jan 27, 1998
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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