

**K974085 COBE OXYGENATOR PRODUCTS**Jan 27, 1998  
90 days to decisionK974085 · 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	<b>Cobe Cardiovascular, Inc.</b>
Location	Arvada, CO, US
Contact	LYNNE LEONARD
510(k) history	43 submissions · 43 cleared · 1992-2005

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k974085/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026