

**K880021 COBE CML3**Apr 1, 1988  
87 days to decisionK880021 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k880021/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jan 5, 1988
Decision date	Apr 1, 1988
Days to decision	87 days
Third-party review	No

**APPLICANT**

---

Company	<b>Cobe Laboratories, Inc.</b>
Location	Mchenry, IL, US
Contact	DENNIS BRUNER,PHD
Website	<a href="https://www.gambro.com">https://www.gambro.com</a>
510(k) history	77 submissions · 77 cleared · 1976-1993

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k880021/> 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 26, 2026