

**K964043 COBE OPTIMA AND COBE CML DUO MEMBRANE  
OXYGENATORS**Sep 29, 1997  
355 days to decisionK964043 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k964043/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Oxygenator, Cardiopulmonary Bypass (DTZ) |
| Date received         | Oct 9, 1996                              |
| Decision date         | Sep 29, 1997                             |
| Days to decision      | 355 days                                 |
| Third-party review    | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Cobe Cardiovascular, Inc.</b>        |
| Location       | Arvada, CO, US                          |
| Contact        | MARY L ARMSTRONG                        |
| 510(k) history | 43 submissions · 43 cleared · 1992-2005 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964043/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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