

**K823343 OXYGENATOR 10**Dec 15, 1982  
37 days to decisionK823343 · Product code: **DTZ** · CardiovascularSource: <https://www.510kdatabase.net/k823343/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Oxygenator, Cardiopulmonary Bypass (DTZ) |
| Date received         | Nov 8, 1982                              |
| Decision date         | Dec 15, 1982                             |
| Days to decision      | 37 days                                  |
| Third-party review    | No                                       |

**APPLICANT**

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| Company        | <b>Gambro, Inc.</b>                     |
| Location       | Mchenry, IL, US                         |
| 510(k) history | 86 submissions · 86 cleared · 1976-2009 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k823343/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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