

**K863515 MODIFIED SARNS OXYGENATOR SYSTEM**Nov 18, 1986  
69 days to decisionK863515 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k863515/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Oxygenator, Cardiopulmonary Bypass (DTZ) |
| Date received         | Sep 10, 1986                             |
| Decision date         | Nov 18, 1986                             |
| Days to decision      | 69 days                                  |
| Third-party review    | No                                       |

**APPLICANT**

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|----------------|---|
| Company        | <b>3M Health Care, Sarns</b>            |
| Location       | Mchenry, IL, US                         |
| Contact        | MARSHALL SMITH                          |
| 510(k) history | 76 submissions · 76 cleared · 1976-1996 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k863515/>; 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 July 4, 2026