

K911227 NEW STERILITY CHARACTER/SARNS OXYGENATOR PRODUCTSMay 29, 1991
70 days to decisionK911227 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k911227/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oxygenator, Cardiopulmonary Bypass (DTZ) |
| Date received | Mar 20, 1991 |
| Decision date | May 29, 1991 |
| Days to decision | 70 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | 3M Health Care, Sarns |
| Location | Mchenry, IL, US |
| Contact | CATHY L SIMPSON |
| 510(k) history | 76 submissions · 76 cleared · 1976-1996 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k911227/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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