FDA 510(k) Premarket Notification

# K895393 SARNS INGANT MEMBRANE OXYGENATOR

**CLEARED**

Dec 4, 1989
90 days to decision

K895393 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k895393/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oxygenator, Cardiopulmonary Bypass (DTZ) |
| Date received | Sep 5, 1989 |
| Decision date | Dec 4, 1989 |
| Days to decision | 90 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |

## APPLICANT

| | |
|---|---|
| Company | **3M Company** |
| Location | White City, OR, US |
| Contact | DENISE D SHIMOKCHI |
| Website | http://www.3m.com/ |
| 510(k) history | 331 submissions · 322 cleared · 1976-2025 |