

K922933 SORIN MONOLYRH INTEGRATED MEMBRANE LUNGNov 30, 1992
165 days to decisionK922933 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k922933/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oxygenator, Cardiopulmonary Bypass (DTZ) |
| Date received | Jun 18, 1992 |
| Decision date | Nov 30, 1992 |
| Days to decision | 165 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Sorin Biomedica, Fiat, USA, Inc. |
| Location | Mchenry, IL, US |
| Contact | LORI E ADELS |
| 510(k) history | 20 submissions · 20 cleared · 1980-1994 |

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