

K945065 DIDECO FLEXIBLE RESERVOIR -- PRODUCT DESIGNATION 5063May 19, 1995
217 days to decisionK945065 · Product code: DTN · Cardiovascular
Source: <https://www.510kdatabase.net/k945065/>**SUBMISSION DETAILS**

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| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Reservoir, Blood, Cardiopulmonary Bypass (DTN) |
| Date received | Oct 14, 1994 |
| Decision date | May 19, 1995 |
| Days to decision | 217 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Sorin Biomedical, Inc. |
| Location | Irvine, CA, US |
| Contact | RONALD S WARREN |
| 510(k) history | 15 submissions · 15 cleared · 1993-1999 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k945065/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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