

**K061527 CARD 43 CARDIOTOMY RESERVOIR WITH
PHOSPHORYLCHOLINE COATING**Jun 27, 2006
25 days to decisionK061527 · Product code: **DTN** · Cardiovascular
Source: <https://www.510kdatabase.net/k061527/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Reservoir, Blood, Cardiopulmonary Bypass (DTN) |
| Date received | Jun 2, 2006 |
| Decision date | Jun 27, 2006 |
| Days to decision | 25 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Sorin Group Italia S.R.L. |
| Location | Mirandola, IT |
| Contact | BARRY SALL |
| 510(k) history | 61 submissions · 61 cleared · 1995-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061527/>. Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026