

**K050111 SMARXT BMR 1900 CLOSED VENOUS RESERVOIR
BAG**Mar 8, 2005
49 days to decisionK050111 · Product code: **DTN** · Cardiovascular
Source: <https://www.510kdatabase.net/k050111/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Reservoir, Blood, Cardiopulmonary Bypass (DTN) |
| Date received | Jan 18, 2005 |
| Decision date | Mar 8, 2005 |
| Days to decision | 49 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Cobe Cardiovascular, Inc. |
| Location | Arvada, CO, US |
| Contact | EDWARD E NEWTON |
| 510(k) history | 43 submissions · 43 cleared · 1992-2005 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050111/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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