

K033800 CAPIOX CARDIOTOMY RESERVOIRFeb 10, 2004
67 days to decisionK033800 · Product code: **DTN** · CardiovascularSource: <https://www.510kdatabase.net/k033800/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Reservoir, Blood, Cardiopulmonary Bypass (DTN) |
| Date received | Dec 5, 2003 |
| Decision date | Feb 10, 2004 |
| Days to decision | 67 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Terumo Cardiovascular Systems Corporation |
| Location | Elkton, MD, US |
| Contact | GARRY A COURTNEY |
| 510(k) history | 29 submissions · 29 cleared · 2002-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033800/> 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 May 14, 2026