

K894664 CAPIOX HARDSHELL VENOUS RESERVOIRApr 20, 1990
270 days to decisionK894664 · Product code: **DTN** · CardiovascularSource: <https://www.510kdatabase.net/k894664/>**SUBMISSION DETAILS**

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| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Reservoir, Blood, Cardiopulmonary Bypass (DTN) |
| Date received | Jul 24, 1989 |
| Decision date | Apr 20, 1990 |
| Days to decision | 270 days |
| Third-party review | No |

APPLICANT

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|----------------|---|
| Company | Terumo Medical Corp. |
| Location | Elkton, MD, US |
| Contact | GEORGE MOMODA |
| 510(k) history | 143 submissions · 143 cleared · 1980-2011 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k894664/>; 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 27, 2026