

K013526 CAPIOX RX HARDSHELL RESERVOIRNov 15, 2001
23 days to decisionK013526 · Product code: **DTN** · CardiovascularSource: <https://www.510kdatabase.net/k013526/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Oct 23, 2001
Decision date	Nov 15, 2001
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Cardiovascular Systems Corp.
Location	Elkton, MD, US
Contact	GARRY A COURTNEY
510(k) history	43 submissions · 43 cleared · 2000-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013526/> 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 25, 2026