

**K030449 MODIFICATION TO CAPIOX SX10 HARDSHELL
RESERVOIR**Mar 5, 2003
22 days to decisionK030449 · Product code: **DTN** · Cardiovascular
Source: <https://www.510kdatabase.net/k030449/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Feb 11, 2003
Decision date	Mar 5, 2003
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Corp.
Location	Somerset, NJ, US
Contact	GARRY A COURTNEY
510(k) history	21 submissions · 21 cleared · 1991-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k030449/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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