

K002238 CAPIOX SX HARDSHELL RESERVOIR WITH X-COATINGAug 22, 2000
29 days to decisionK002238 · Product code: **DTN** · Cardiovascular
Source: <https://www.510kdatabase.net/k002238/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Jul 24, 2000
Decision date	Aug 22, 2000
Days to decision	29 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/k002238/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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