

K062381 CAPIOX RX OXYGENATOR WITH OR WITHOUT RESERVOIRAug 24, 2006
9 days to decisionK062381 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k062381/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Aug 15, 2006
Decision date	Aug 24, 2006
Days to decision	9 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/k062381/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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