

**K130359 CAPIOX SX18 HOLLOW FIBER OXYGENATOR WITH
DETACHABLE HARDSHELL RESERVOIR, CAPIOX SX25
HOLLOW FIBER OXGENATOR WITH DETACHA**

Mar 13, 2013
28 days to decision

K130359 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k130359/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Feb 13, 2013
Decision date	Mar 13, 2013
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k130359/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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