

**K130520 CAPIOX FX15 AND FX25 HOLLOW FIBER
OXYGENATOR/RESERVOIR**Mar 13, 2013
13 days to decisionK130520 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k130520/>**SUBMISSION DETAILS**

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

APPLICANT

Company	Ashitaka Factory of Terumo Corp.
Location	Fujinomiya Shizuoka, JP
Contact	EILEEN DORSEY
510(k) history	3 submissions · 3 cleared · 2013-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130520/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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