

**K130493 CAPIOX RX05 HOLLOW FIBER
OXYGENATOR/RESERVOIR**Mar 13, 2013
15 days to decisionK130493 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k130493/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Feb 26, 2013
Decision date	Mar 13, 2013
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Corporation
Location	Shibuya-Ku, Tokyo, JP
Contact	GARRY A COURTNEY, MBA, RAC
510(k) history	13 submissions · 13 cleared · 2012-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130493/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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