

**K071494 CAPIOX FX15 AND FX25 HOLLOW FIBER
OXYGENATOR AND ARTERIAL FILTER**Jul 16, 2007
47 days to decisionK071494 · Product code: DTZ · Cardiovascular
Source: <https://www.510kdatabase.net/k071494/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	May 30, 2007
Decision date	Jul 16, 2007
Days to decision	47 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Corp.
Location	Somerset, NJ, US
Contact	GARY COURTNEY
510(k) history	21 submissions · 21 cleared · 1991-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k071494/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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