

K151791 Terumo Capiox FX15 Advance Oxygenator with Integrated Arterial Filter and Reservoir, Terumo Capiox FX25 Advance Oxygenator with Integrated Arterial Filter and ReservoirNov 19, 2015
141 days to decisionK151791 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k151791/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jul 1, 2015
Decision date	Nov 19, 2015
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Cardiovascular Systems Corporation
Location	Elkton, MD, US
Contact	JAIME LEE
510(k) history	29 submissions · 29 cleared · 2002-2024

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