

K151389 Terumo Capiox FX15 Advance Oxygenator with Integrated Arterial Filter and Hardshell ReservoirOct 20, 2015
147 days to decisionK151389 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k151389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	May 26, 2015
Decision date	Oct 20, 2015
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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