

K153140 Terumo Capiox SX18 Oxygenator/ Hardshell Reservoir, Terumo Capiox SX18 Oxygenator/ Hardshell Reservoir with Xcoating, Terumo Capiox SX25 Oxygenator/Hardshell Reservoir, Terumo Capiox SX25 Oxygenator/Hardshell Reservoir with XcoatingDec 2, 2015
33 days to decisionK153140 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k153140/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Oct 30, 2015
Decision date	Dec 2, 2015
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Cardiovascular Systems Corp.
Location	Elkton, MD, US
Contact	JOSHUA P. EWING
510(k) history	43 submissions · 43 cleared · 2000-2015

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