

K153143 Capiox Advance Hardshell ReservoirDec 2, 2015
33 days to decisionK153143 · Product code: **DTN** · Cardiovascular
Source: <https://www.510kdatabase.net/k153143/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
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 Corporation
Location	Elkton, MD, US
Contact	Tierra A. Brown
510(k) history	29 submissions · 29 cleared · 2002-2024

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