

K180950 Terumo Capiox NX19 Oxygenator with Reservoir (east Orientation), Terumo Capiox NX19 Oxygenator with Reservoir (west Orientation), Terumo Capiox NX19 Oxygenator (east Orientation), Terumo Capiox NX19 Oxygenator (west Orientation)Jun 22, 2018
72 days to decisionK180950 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k180950/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Apr 11, 2018
Decision date	Jun 22, 2018
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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