FDA 510(k) Premarket Notification

K130280 CAPIOX FX HOLLOW FIBER OXYGENATOR W/ RESERVOIR

CLEARED

Mar 13, 2013
36 days to decision

K130280 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k130280/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Feb 5, 2013
Decision date	Mar 13, 2013
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Terumo Corporation**
Location	Shibuya-Ku, Tokyo, JP
Contact	GARRY A COURTNEY, MBA, RAC
510(k) history	13 submissions · 13 cleared · 2012-2026