FDA 510(k) Premarket Notification

CLEARED

K130520 CAPIOX FX15 AND FX25 HOLLOW FIBER OXYGENATOR/RESERVOIR

Mar 13, 2013
13 days to decision

K130520 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k130520/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Feb 28, 2013
Decision date	Mar 13, 2013
Days to decision	13 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ashitaka Factory of Terumo Corp.**
Location	Fujinomiya Shizuoka, JP
Contact	EILEEN DORSEY
510(k) history	3 submissions · 3 cleared · 2013-2015