FDA 510(k) Premarket Notification

CLEARED

K133658 CDI BLOOD PARAMETER MONITORING SYSTEM 500

Jul 25, 2014
240 days to decision

K133658 · Product code: **DRY** · Cardiovascular
Source: https://www.510kdatabase.net/k133658/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY)
Date received	Nov 27, 2013
Decision date	Jul 25, 2014
Days to decision	240 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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