FDA 510(k) Premarket Notification

K182110 CDI Blood Parameter Monitoring System 550

CLEARED

Nov 2, 2018
88 days to decision

K182110 · Product code: **DRY** · Cardiovascular
Source: https://www.510kdatabase.net/k182110/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY)
Date received	Aug 6, 2018
Decision date	Nov 2, 2018
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Terumo Cardiovascular Systems Corporation**
Location	Elkton, MD, US
Contact	Bryan K. Hann
510(k) history	29 submissions · 29 cleared · 2002-2024