FDA 510(k) Premarket Notification

K234065 CDI OneView Monitoring System

CLEARED

Apr 25, 2024
125 days to decision

K234065 · Product code: **DRY** · Cardiovascular
Source: https://www.510kdatabase.net/k234065/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY)
Date received	Dec 22, 2023
Decision date	Apr 25, 2024
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Terumo Cardiovascular Systems Corporation**
Location	Elkton, MD, US
Contact	Rahul Reddy Chinkeri
510(k) history	29 submissions · 29 cleared · 2002-2024