

K234065 CDI OneView Monitoring SystemApr 25, 2024
125 days to decisionK234065 · Product code: **DRY** · CardiovascularSource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k234065/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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