FDA 510(k) Premarket Notification

K234003 The Circadia C200 System

CLEARED

May 30, 2024
163 days to decision

K234003 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k234003/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Dec 19, 2023
Decision date	May 30, 2024
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Circadia Technologies, Ltd.**
Location	Croydon, GB
Contact	Erhan Ilhan
510(k) history	2 submissions · 2 cleared · 2020-2024