FDA 510(k) Premarket Notification

K252676 The Circadia C300 System (C300)

CLEARED

Feb 3, 2026
162 days to decision

K252676 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k252676/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Aug 25, 2025
Decision date	Feb 3, 2026
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Circadia Health, Inc.**
Location	El Segundo, CA, US
Contact	Timo Lauteslager
510(k) history	1 submissions · 1 cleared · 2026-2026