

K252676 The Circadia C300 System (C300)Feb 3, 2026
162 days to decisionK252676 · Product code: **DRT** · CardiovascularSource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252676/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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