

K843533 CARDIAC EVENT RECORDERJun 28, 1985
294 days to decisionK843533 · Product code: **DRT** · CardiovascularSource: <https://www.510kdatabase.net/k843533/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiometer & Rate Alarm) (DRT)
Date received	Sep 7, 1984
Decision date	Jun 28, 1985
Days to decision	294 days
Third-party review	No

APPLICANT

Company	Cryo2 Corp.
Location	Walker, MI, US
510(k) history	2 submissions · 2 cleared · 1984-1985

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k843533/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026