

K233110 Carnation Ambulatory MonitorNov 22, 2023
56 days to decisionK233110 · Product code: **DSH** · Cardiovascular
Source: <https://www.510kdatabase.net/k233110/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Sep 27, 2023
Decision date	Nov 22, 2023
Days to decision	56 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Bardy Diagnostics, Inc.
Location	Vashon Island, WA, US
Contact	Ben Hornsey
510(k) history	7 submissions · 7 cleared · 2014-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233110/> 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 26, 2026