

K191000 Carnation Ambulatory MonitorMay 16, 2019
30 days to decisionK191000 · Product code: **DSH** · Cardiovascular
Source: <https://www.510kdatabase.net/k191000/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Apr 16, 2019
Decision date	May 16, 2019
Days to decision	30 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191000/> 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