

**K210036 Carnation Ambulatory Monitor (CAM)**Feb 5, 2021  
30 days to decisionK210036 · Product code: **DSH** · CardiovascularSource: <https://www.510kdatabase.net/k210036/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Jan 6, 2021
Decision date	Feb 5, 2021
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Bardy Diagnostics, Inc.</b>
Location	Vashon Island, WA, US
Contact	Jocelyn Kersten
510(k) history	7 submissions · 7 cleared · 2014-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210036/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026