

K192556 Carnation Ambulatory MonitorOct 17, 2019
30 days to decisionK192556 · Product code: **DSH** · Cardiovascular
Source: <https://www.510kdatabase.net/k192556/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Sep 17, 2019
Decision date	Oct 17, 2019
Days to decision	30 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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