

K191471 Carnation Ambulatory MonitorAug 30, 2019
88 days to decisionK191471 · Product code: **DSH** · Cardiovascular
Source: <https://www.510kdatabase.net/k191471/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Jun 3, 2019
Decision date	Aug 30, 2019
Days to decision	88 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

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