

K200870 Carnation Ambulatory MonitorMay 1, 2020
30 days to decisionK200870 · Product code: **DSH** · Cardiovascular
Source: <https://www.510kdatabase.net/k200870/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Apr 1, 2020
Decision date	May 1, 2020
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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