

K121197 BODYGUARDIAN SYSTEM BODYGUARDIAN CONTROL UNIT BODYGUARDIAN CONNECT

Aug 10, 2012
113 days to decision

K121197 · Product code: **DSI** · Cardiovascular
Source: <https://www.510kdatabase.net/k121197/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Apr 19, 2012
Decision date	Aug 10, 2012
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Preventice, Inc.
Location	Rochester, MN, US
Contact	DREW PALIN
510(k) history	1 submissions · 1 cleared · 2012-2012

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k121197/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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