

K243349 BodyGuardian Remote Monitoring System (BGRMS v3.0)

Jan 23, 2026
452 days to decision

K243349 · Product code: **DSI** · Cardiovascular
Source: <https://www.510kdatabase.net/k243349/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Oct 28, 2024
Decision date	Jan 23, 2026
Days to decision	452 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Cardiac Diagnostic Technologies, Inc.
Location	Rochester, MN, US
Contact	Meghan Styles
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k243349/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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