

K111159 HEARTCHECK PEN HANDHELD ECG WITH GEMS HOME

Dec 22, 2011
241 days to decision

K111159 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k111159/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Apr 25, 2011
Decision date	Dec 22, 2011
Days to decision	241 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardiocomm Solutions, Inc.
Location	Victoria, B.C., CA
Contact	JONATHAN WARD
510(k) history	9 submissions · 9 cleared · 2002-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k111159/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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