

**K181310 HeartCheck Cardi Beat ECG Monitor with GEMS
Mobile**Feb 22, 2019
281 days to decisionK181310 · Product code: **DXH** · Cardiovascular
Source: <https://www.510kdatabase.net/k181310/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	May 17, 2018
Decision date	Feb 22, 2019
Days to decision	281 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181310/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 18, 2026