FDA 510(k) Premarket Notification

CLEARED

K181310 HeartCheck Cardi Beat ECG Monitor with GEMS Mobile

Feb 22, 2019
281 days to decision

K181310 · 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