FDA 510(k) Premarket Notification

K172801 ECG SENTINEL System

CLEARED

Oct 18, 2017
30 days to decision

K172801 · Product code: **DXH** · Cardiovascular
Source: https://www.510kdatabase.net/k172801/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Sep 18, 2017
Decision date	Oct 18, 2017
Days to decision	30 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Cardiomedix, Inc.**
Location	Evanston, IL, US
Contact	Zipora David
510(k) history	1 submissions · 1 cleared · 2017-2017