

K170506 ECG Check - Universal, ECG Check - Universal PlusOct 2, 2017
223 days to decisionK170506 · Product code: **DXH** · Cardiovascular
Source: <https://www.510kdatabase.net/k170506/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Feb 21, 2017
Decision date	Oct 2, 2017
Days to decision	223 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardiac Designs, Inc.
Location	Spring, TX, US
Contact	James Tassone
510(k) history	1 submissions · 1 cleared · 2017-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170506/> 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 May 31, 2026