

K083535 HEARTRAK SMART ECATDec 15, 2008
17 days to decisionK083535 · Product code: **DXH** · Cardiovascular
Source: <https://www.510kdatabase.net/k083535/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Nov 28, 2008
Decision date	Dec 15, 2008
Days to decision	17 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Universal Medical, Inc.
Location	Philadelphia, PA, US
Contact	JOYCE W DEAN
510(k) history	8 submissions · 8 cleared · 1995-2008

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