

K130878 CLOUDEKGApr 4, 2014
371 days to decisionK130878 · Product code: **DXH** · Cardiovascular
Source: <https://www.510kdatabase.net/k130878/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Mar 29, 2013
Decision date	Apr 4, 2014
Days to decision	371 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Makromed, Inc.
Location	Salem, NH, US
Contact	BARRY V ASHAR
510(k) history	1 submissions · 1 cleared · 2014-2014

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