

**K113045 BIOHARNESS**Aug 14, 2012  
306 days to decisionK113045 · Product code: **MHX** · CardiovascularSource: <https://www.510kdatabase.net/k113045/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Oct 13, 2011
Decision date	Aug 14, 2012
Days to decision	306 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zephyr Technology Corporation</b>
Location	Annapolis, MD, US
Contact	RICHARD KEEN
Website	<a href="http://zephyranywhere.com/">http://zephyranywhere.com/</a>
510(k) history	4 submissions · 4 cleared · 2010-2013

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113045/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 8, 2026