

**K100040 BIOHARNESS**Dec 3, 2010  
330 days to decisionK100040 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k100040/>**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	Jan 7, 2010
Decision date	Dec 3, 2010
Days to decision	330 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zephyr Technology Corporation</b>
Location	Annapolis, MD, US
Contact	CODE CUBITT
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/k100040/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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