

**K081140 VISENSIA**Jul 17, 2008  
86 days to decisionK081140 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k081140/>**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	Apr 22, 2008
Decision date	Jul 17, 2008
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Obs Medical</b>
Location	Carmel, IN, US
Contact	WAYNE NETHERCUTT
510(k) history	3 submissions · 3 cleared · 2007-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081140/> 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 19, 2026