

**K130208 BERNOULLI ENTERPRISE SOFTWARE**Dec 20, 2013  
326 days to decisionK130208 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k130208/>**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 28, 2013
Decision date	Dec 20, 2013
Days to decision	326 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Cardiopulmonary Corp.</b>
Location	Milford, CT, US
Contact	UREY KANG
510(k) history	9 submissions · 6 cleared · 1995-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130208/> 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 May 24, 2026