

**K112877 COMEN MULTI-PARAMETER PATIENT MONITOR**Nov 7, 2012  
404 days to decisionK112877 · Product code: **MWI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k112877/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Sep 30, 2011
Decision date	Nov 7, 2012
Days to decision	404 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Goldway Us, Inc.</b>
Location	San Jose, CA, US
Contact	JIMMY WU
510(k) history	4 submissions · 4 cleared · 2003-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112877/> 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 9, 2026