

**K063547 CALYSTO SERIES IV PHYSIO-MONITORING AND INFORMATION SYSTEM**Dec 21, 2006  
27 days to decisionK063547 · Product code: **MWI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k063547/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Nov 24, 2006
Decision date	Dec 21, 2006
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Witt Biomedical Corp</b>
Location	Melbourne, FL, US
Contact	JAMES LUKER
510(k) history	5 submissions · 5 cleared · 2004-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k063547/>; 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 18, 2026