

**K062095 MCARE 300 VITAL SIGNS MONITOR, MODEL 91220**Sep 29, 2006  
67 days to decisionK062095 · Product code: **MHX** · CardiovascularSource: <https://www.510kdatabase.net/k062095/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jul 24, 2006
Decision date	Sep 29, 2006
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spacelabs Medical, Inc.</b>
Location	Hamden, CT, US
Contact	DAVID J GERAGHTY
510(k) history	35 submissions · 34 cleared · 1993-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k062095/> 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 25, 2026