

**K082045 MODIFICATION TO MCARE 300 VITAL SIGNS
MONITOR, MODEL 91220**Aug 1, 2008
14 days to decisionK082045 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k082045/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jul 18, 2008
Decision date	Aug 1, 2008
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spacelabs Medical, Inc.
Location	Hamden, CT, US
Contact	TIM DAVIS
510(k) history	35 submissions · 34 cleared · 1993-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082045/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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