

K123472 CIMVA UNIVERSALMar 5, 2013
112 days to decisionK123472 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k123472/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Nov 13, 2012
Decision date	Mar 5, 2013
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Therapeutic Monitoring Systems (Tms), Inc.
Location	Alameda, CA, US
Contact	CRAIG J COOMBS
510(k) history	1 submissions · 1 cleared · 2013-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123472/> Data sourced from FDA 510(k) public records (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. - Generated June 9, 2026