

K231086 CPM SystemDec 22, 2023
249 days to decisionK231086 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k231086/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Apr 17, 2023
Decision date	Dec 22, 2023
Days to decision	249 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Analog Devices, Inc.
Location	Wilmington, MA, US
Contact	Sam Rajkumar
Website	http://www.analog.com
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231086/> 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 May 26, 2026