FDA 510(k) Premarket Notification

# K231086 CPM System

**CLEARED**

Dec 22, 2023
249 days to decision

K231086 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k231086/

## SUBMISSION DETAILS

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|---|---|
| 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 |