

K233446 AMC Health CareConsoleSep 27, 2024
344 days to decisionK233446 · Product code: **MWI** · CardiovascularSource: <https://www.510kdatabase.net/k233446/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Oct 19, 2023
Decision date	Sep 27, 2024
Days to decision	344 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Amc Health
Location	New York, NY, US
Contact	Hernani Castro
510(k) history	2 submissions · 2 cleared · 2016-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233446/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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