FDA 510(k) Premarket Notification

K233446 AMC Health CareConsole

CLEARED

Sep 27, 2024
344 days to decision

K233446 · Product code: **MWI** · Cardiovascular
Source: 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