FDA 510(k) Premarket Notification

K233354 WVSM Pro (Series) (500-0030-XX)

CLEARED

Jun 26, 2024
271 days to decision

K233354 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k233354/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Sep 29, 2023
Decision date	Jun 26, 2024
Days to decision	271 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Athena Gtx, Inc.**
Location	Johnson, IA, US
Contact	Sean Mahoney
510(k) history	1 submissions · 1 cleared · 2024-2024