

K191989 WVSM (Wireless Vital Signs Monitor) RWC + miniCapJan 29, 2020
188 days to decisionK191989 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k191989/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jul 25, 2019
Decision date	Jan 29, 2020
Days to decision	188 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Athena Gtx
Location	Des Moines, IA, US
Contact	Sean Mahoney
510(k) history	7 submissions · 7 cleared · 2010-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191989/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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