FDA 510(k) Premarket Notification

CLEARED

K191989 WVSM (Wireless Vital Signs Monitor) RWC + miniCap

Jan 29, 2020
188 days to decision

K191989 · 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