

**K182401 B.O.L.T Base Unit, B.O.L.T Non-Invasive Blood Pressure (NIBP) Cuff, B.O.L.T Infrared Radiation Energy Technology(IRT) Thermometer probe, B.O.L.T Pulse Oximeter(SPO2) probe, B.O.L.T Gluchobin Blood Glucose, Total Cholesterol and Hemoglobin meter**Aug 28, 2019  
358 days to decisionK182401 · Product code: **MWI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k182401/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Sep 4, 2018
Decision date	Aug 28, 2019
Days to decision	358 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Amzetta Technologies Private Limited</b>
Location	Chennai, IN
Contact	Sridharan Mani
510(k) history	1 submissions · 1 cleared · 2019-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182401/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026