September 6, 2019

AmZetta Technologies Private Limited
Sridharan Mani
Chief Executive Officer
Kumaran Nagar, Semmanchery, Off Rajiv Gandhi Salai (OMR)
Chennai, 600 119 In

Re: K182401
Trade/Device Name: B.O.L.T (Body Life Tracker)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DXN, DQA, FLL
Dated: August 29, 2018
Received: September 4, 2018

Dear Sridharan Mani:

This letter corrects our substantially equivalent letter of August 28, 2019.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen C. Browning -S5

Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182401

Device Name
B.O.L.T (Body Life Tracker)

Indications for Use *(Describe)*
B.O.L.T model (VA01) Base unit with it`s accessory devices attachment (VA01-0, VA01-1 and VA01-2) and the B.O.L.T application is a patient vitals measuring and monitoring system used for spot-checking and measuring the physiological parameters of adult patients / users (18 years of age or older). The physiological parameters measured and monitored are:
• Non-Invasive Blood Pressure (NIBP), Pulse Rate (PR)
• Oxygen saturation (SpO2), Pulse Rate (PR)
• Body Temperature (TEMP)

B.O.L.T application is downloaded and installed in a Bluetooth enabled smart devices/ computer. The operations of the base unit and the attached devices like start and stop are controlled by the B.O.L.T application and the results are displayed by the B.O.L.T application on the screen of the smart devices/ computer.

This device is applicable for use by an adult and it can be used in a clinical setting like a physician office and also in a home environment for patients to keep track of the physiological parameters mentioned above. Home users are advised to contact their physician if any abnormal values are indicated.

B.O.L.T, NIBP model Base unit (VA01) along with an inflatable cuff (VA01-0) that is wrapped around the upper arm, is a fully automatic, non-invasive, wireless blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual.

B.O.L.T, IRT model Base unit (VA01) along with a thermometer probe (VA01-1) using infrared sensor detects body temperature from the ear canal in the adult population.

B.O.L.T, Pulse Oximeter model Base unit (VA01) along with a pulse oximeter probe (VA01-2) is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) from the fingertip of adult users.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510k Summary

Sponsor Details

AmZetta Technologies Private Limited.,
(Formerly Known As American Megatrends India Private Limited)
Kumaran Nagar, Semmanchery,
Off. Old Mahabalipuram Road
Chennai-600119,
Tamilnadu
India
Phone : +914461240022
Fax : +914461240025
Contact : Sridharan Mani
Title : Chief Executive Officer
Email : sridharanm@amzetta.co.in

Alternate Contact : G. Ketharaman
Title : Unit Head- Healthcare Group
Email : amzusfda@amzetta.co.in

Summary Preparation Date: 22nd July, 2019

Device/s Submitted for FDA 510K Premarket Notification

Trade Name	**B.O.L.T. (Body Life Tracker)**
Product Codes	**B.O.L.T BT1, BT2, BT3, BT4**
Device Model Numbers	**VA01 - B.O.L.T Base Unit** **VA01-0 - B.O.L.T Non-Invasive Blood Pressure(NIBP) Cuff** **VA01-1 - B.OL.T Infrared Radiation Energy Technology (IRT) Thermometer probe** **VA01-2 - B.O.L.T Pulse Oximeter (SPO2) probe**
Common Name	**Patient Physiological Monitor**
Classification Name	**Monitor, Physiological, Patient (without arrhythmia detection or alarms)**
Classification	**Class II**
Product code	**MWI**
Other Product codes	**DQA- Pulse Oximeter** **DXN - Blood Pressure, non-invasive** **FLL -Thermometer, electronic, clinical**
Regulation Number	**21 CFR 870.2300**
Review Panel	**Cardiovascular, General Hospital**

Devices submitted for 510K:

The B.O.L.T Patient Physiological Monitor which is called the B.O.L.T Life tracker is a patient vitals measuring and monitoring device which can be used by home users as well as a clinical setting like physician office for spot-checking and measuring of the following patient's physiological parameters:

- Measurement of the Systolic Blood Pressure, Diastolic Blood Pressure and Pulse Rate (PR), non- invasively;
- Spot measurement of functional blood Oxygen saturation (SpO2) and Pulse Rate (PR), non-invasively; and
- Measurement of the Body Temperature through ear canal, non invasively

The B.O.L.T system is modularly designed and consists of:

- Base unit (model VA01);
- NIBP (Non-Invasive Blood Pressure) Cuff (model VA01-0);
- Infrared Radiation Energy Technology-IRT Thermometer (model VA01-1); and
- Pulse Oximeter (VA01-2).

The system is packaged as a complete system with all the devices included or alternatively packaged separately with the base unit and individual device/s. When individually packaged, the system is supplied with a base unit and the required device/s. The different product bundle along with the product code/name is given below,

B.O.L.T. Product Name/code	**Package Bundle**	**Devices model numbers**
BT1	Base Unit and NIBP	VA01 and VA01-0
BT2	Base Unit, NIBP and Body Temperature	VA01, VA01-0 and VA01-1
BT3	Base Unit, NIBP and SpO2	VA01,VA01-0 and VA01-2
BT4	NIBP, Body Temperature and SpO2	VA01, VA01-0, VA01-1 and VA01-2

Device Description:

The B.O.L.T patient monitor system base unit VA01 is elegantly designed with small form factor. The devices NIBP, IRT thermometer and Pulse Oximeter connects to the base unit. The device has two LED indicators that display power status and Bluetooth connectivity status. The device has an on/off slide switch on the side and USB power socket. The device has one accessories port with Lemo connector to connect IRT Thermometer and Pulse Oximeter, one at a time. There are two other ports to connect the twin tubes of the NIBP Cuff. The base unit has a rechargeable lithium polymer battery and device should be used only in battery mode and it should not be used while charging. The power adapter is given only for charging the device.

The B.O.L.T, NIBP device model VA01-0 connects to the VA01 Base unit's twin port and measures both systolic and diastolic blood pressure and pulse rate via a standard oscillometric method. The oscillometric method senses the vibrating signal via the closed air pipe system and utilizes a microcontroller in the base unit to automatically sense the characteristics of the pulse

signal. Unlike with the traditional measuring method, based o6i the Korotkov sound, with the oscillometric method the use of a stethoscope is not required. Through simple calculations, this method provides accurate blood pressure readings: the systolic pressure is defined as the blood pressure when the cuff pressure oscillating amplitude begins to increase, while the diastolic blood pressure is defined as the pressure when the cuff pressure oscillating amplitude stops decreasing. The device includes a plastic enclosure and external wraparound cuff, and it requires an external device (e.g. a smartphone) to display results and perform user interaction.

The IRT Thermometer module of B.O.LT., model VA01-1, patient monitoring system is an electronic thermometer using an infrared sensor (thermopile) to detect body temperature from the ear canal. Its operation is based on measuring the natural thermal radiation emanating from the tympanic membrane and the adjacent surfaces. The unit measures the infrared energy emitting from the middle ear and the surrounding tissue. This energy is absorbed by lenses and converted into temperature values. The IRT electronic thermometer accessory (VA01-1) connects to the accessory connector of the B.O.L.T Base unit (VA01) patient monitoring system and readout value is displayed on the connected Bluetooth device like a Smart Phone, tablet or personal computer**.**

The Infrared Ear thermometer module of B.O.L.T, model VA01-1 patient monitoring system consists of the following parts:

- Thermopile Sensor
- Application-Specific Integrated Circuit
- Lens
- Probe cover (Single use and probe cover to be disposed after each measurement)

The B.O.L.T model VA01-2 fingertip pulse oximeter accessory device features a small form factor, low power consumption, a convenient operation, and portability. It is only necessary for a patient to put one of his/her fingers into the fingertip clips for measurement. The fingertip pulse oximeter accessory device connects to the accessory connector of the B.O.L.T VA01 base unit. The readout value Spo2(%) and Pulse rate values are displayed on the connected Bluetooth device like a Smart Phone, tablet or personal computer.

The user manual which is provided with the device provides the detailed specifications.

The system is controlled and operated via the B.O.L.T application which is downloaded and installed in a Bluetooth enabled smartphone/tablet/computer. The B.O.L.T application is supported for the following versions of Android/IOS and Windows operating system.

- The Android OS version 4.0 or higher.
- The iOS version 7 or higher.
- The Windows OS version 8 or higher

The software communicates with the base unit (VA01) through Bluetooth communication to the connected smartphone/tablet/computer. The user has to pair the base unit with handheld mobile devices or computers through Bluetooth and use the Software application to operate and control the devices attached to the base unit. Functions like activating and stopping the device and display of the test value are all performed by the B.O.L.T application residing in the Bluetooth connected smartphone/tablet/computer. The device/s is connected to the accessory port of the base unit. The base unit takes signals from the connected device like NIBP Cuff, Pulse oximeter, IRT Thermometer. The software and firmware of the B.O.L.T patient monitoring system, process the data from the accessory devices, then display the parameters/measured data on the screen

of a wirelessly connected Bluetooth device like a smartphone/ tablet/ personal computer. B.O.L.T application can hold any number of records and recognized by user ID. The number of records is limited by the data storage capacity of the secured cloud infrastructure. FCC grant is obtained under FCC ID: 2AFV6-AMI-BU-2.

The data collected from devices can be securely uploaded/stored in a secured cloud. The secured cloud is HIPAA compliant and hosted in a HIPAA compliant data Centre. All the protected health information and the physiological data of a user/patient is encrypted at rest. The communication over the internet to the cloud utilizes the HTTPS/TLS protocol. The B.O.L.T is also packaged with a SDK (Software Development Kit) to integrate the reading from the devices to an external system like a Care Portal/Electronic Medical Record software system

Indications for use:

B.O.L.T model (VA01) Base unit with it`s accessory devices attachment (VA01-0, VA01-1 and VA01-2) and the B.O.L.T application is a patient vitals measuring and monitoring system used for spot-checking and measuring the physiological parameters of adult patients / users (18 years of age or older). The physiological parameters measured and monitored are:

- Non-Invasive Blood Pressure (NIBP), Pulse Rate (PR)
- Oxygen saturation (SpO2), Pulse Rate (PR)
- Body Temperature (TEMP)

B.O.L.T application is downloaded and installed in a Bluetooth enabled smart devices/ computer. The operations of the base unit and the attached devices like start and stop are controlled by the B.O.L.T application and the results are displayed by the B.O.L.T application on the screen of the smart devices/ computer.

This device is applicable for use by an adult and it can be used in a clinical setting like a physician office and also in a home environment for patients to keep track of the physiological parameters mentioned above. Home users are advised to contact their physician if any abnormal values are indicated.

B.O.L.T, NIBP model Base unit (VA01) along with an inflatable cuff (VA01-0) that is wrapped around the upper arm, is a fully automatic, non-invasive, wireless blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual.

B.O.L.T, IRT model Base unit (VA01) along with a thermometer probe (VA01-1) using infrared sensor detects body temperature from the ear canal in the adult population.

B.O.L.T, Pulse Oximeter model Base unit (VA01) along with a pulse oximeter probe (VA01-2) is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) from the fingertip of adult users.

Contraindications:

The following contraindications are mentioned in the labelling information**:**
The B.O.L.T device is not recommended for people with serious arrhythmia. Consult your doctor during pregnancy, arrhythmia, and arteriosclerosis. The analyzed results from the devices are not

sufficient to make a correct diagnosis of the patient`s clinical condition. A detailed clinical history of the patient together with the results of any other tests suggested by a doctor is also required. This device is contraindicated for any person who is connected to a wearable or implantable electronic device or instrument, such as a pacemaker or defibrillator.

Substantial Equivalence comparison of the B.O.L.T NIBP with predicate Devices:

The B.O.L.T NIBP model VA01- 0 is compared against the following predicate devices:

K133125 Withings Blood Pressure Monitor, Upper Arm Type: BP-801 model BP01 from Withings

K120672 Blood Health BPS Fully Automatic Arm Cuff Wireless Blood Pressure dock model KD 936 from Andon Health

Comparison Item	**Submitted proposed device**	**Predicate device 1**	**Predicate device 2**
Applicant	AmZetta Technologies Private Limited.	Withings	Andon Health Co., Ltd
Trade Name	B.O.L.T	Withings Blood Pressure Monitor, Upper Arm Type: BP-801	Blood Health BPS Fully Automatic Arm Cuff Wireless Blood Pressure dock
Model Name	B.O.L.T VA01-0	BP-801	KD-936
510K Number	New Listing	K133125	K120672
Technological characteristics	Oscillometric method	Oscillometric method	Oscillometric method
Measuring method	Oscillometric method, automatic inflation and measurement	Oscillometric method, automatic inflation and measurement	Oscillometric method, automatic inflation and measurement
Sensor	Semiconductor gauge sensor	Semiconductor gauge sensor	Semiconductor gauge sensor
Rapid Air release	Through an active electronic control valve	Through an active electronic control valve	Through an active electronic control valve
Cuff tissues	Lycra, Velcro loop, Velcro hook, PU leather, bias	Lycra, Velcro loop, Velcro hook, PU leather, bias	Lycra, Velcro loop, Velcro hook, PU leather, bias
Pressure Accuracy	Pressure:±3mmHg	Pressure:±3mmHg or ±2% of Pressure readout value	Pressure:±3mmHg
Pulse accuracy	±5% of Pressure reading value	±5% of Pressure reading value	±5% of Pressure reading value
System Architecture	Requires an external device to constitute a complete blood pressure measurement system e.g. blood pressure cuff	Independent operation	Requires an external device to constitute a complete blood pressure measurement system

Display an User Interaction	Requires an external device to display results and perform user interaction. Devices supported any Bluetooth enabled smart phone, tablet or personal computer.	LCD monitor and personal computer	Requires an external device to display results and perform user interaction
Communication	Wireless, based on Bluetooth V4.0 + EDR (Bluetooth Low energy)	Wireless, based on Bluetooth V4.0 Dual mode(V2.1 + EDR)	Wireless, based on Bluetooth V3.0 + EDR
Power Source	Rechargeable batteries (Li-Polymer) 3.7 volt,850mAh and DC power 5V, 2A.	Disposable 4xAAA alkaline batteries	Rechargeable batteries (Li-Ion 400 mAh)
Cuff Type and Size	Upper arm type, size: 22 to 42 cm	Upper arm type, size: 22 to 42 cm	Upper arm type, size: 23 to 48 cm
Operating Temperature and Humidity	10 to 40º C Atmospheric**:** 15 to 85% RH non-condensing	10 to 40º C 15 to 90% RH. Atmospheric:86Kpa to 106Kpa Altitude: 2000m	5 to 40º C Atmospheric: <90% RH
Storage Temperature and Humidity	-10 to 55º C Atmospheric: 15 to 85% RH non-condensing	-5 to 70º C 10 to 95% RH. Atmospheric:86Kpa to 106Kpa Altitude: 2000m	-22 to 55º C Atmospheric: <90% RH

Material Make-up of the device:

Comparison Item	Applicant	Predicate Device 1	Predicate Device 2
BP Cuff	Lycra fabric on the rear side, Velcro loop, Velcro hook, PU leather, bias	Lycra, Velcro loop, Velcro hook, PU leather, bias	Lycra, Velcro loop, Velcro hook, PU leather, bias
Rubber tube of BP Cuff	Neoprene (tubing wall)	Neoprene (tubing wall)	Neoprene (tubing wall)

Summary with predicate device:

The principles of operations, core technology and design specifications used in the NIBP module of the B.O.L.T model VA01-0 are similar to the predicate devices except the assembly and the implementation of the core design. A detailed document on the principles of operations, design, assembly and technology characteristics were submitted.

The intended use and the indications for use of the B.O.L.T blood pressure monitor, model VA01-0 as described in its labeling are similar as the two predicate devices and all three devices are intended to be used in similar manner and environments, except B.O.L.T blood pressure system model VA01-0 can be used by the medical professional in a clinical as well as home users.

Patient contact materials, performance, biocompatibility function, mechanical safety, standards met, electrical safety, and EMC are similar**.** The material make up of the B.O.L.T blood pressure monitor, model VA01-0 and the two predicate devices compared are similar and the exception is only in the color of the material.

B.O.L.T blood pressure monitor, model VA01-0 and the predicate devices use Bluetooth to communicate wirelessly with a smartphone, tablet or PC. While B.O.L.T blood pressure monitor uses Bluetooth V4.0 + EDR, predicate device KD-936 uses Bluetooth V3.0+EDR and the Withings Blood Pressure Monitor, Upper Arm Type: BP-801 uses Bluetooth V4.0. The user interface, visual appearance and cuff size for the new device and the predicate devices differ.

AmZetta Technologies Private Limited believe that the B.O.L.T blood pressure monitor model VA01-0 is substantially equivalent to the predicate devices and other products currently in distribution.

Substantial Equivalence comparison of the B.O.L.T IRT Thermometer with predicate Devices:

B.O.L.T IRT Thermometer model VA01-1 is compared against K170219 Microlife Digital Infrared Ear Thermometer model IR1DR1-1 from Microlife Intellectual Property GmbH, Switzerland

Comparison Item	**Submitted proposed device**	**Predicate Device**
Applicant	AmZetta Technologies Private Limited.	Microlife Intellectual Property GmbH, Switzerland
Trade Name	B.O.L.T IRT Thermometer	Microlife Digital Infrared Ear Thermometer
Model Name	B.O.L.T VA01-1	IR1DR1-1
510K Number	New Listing	K170219
Device Measurement Technology	Infrared	Infrared
Measuring method	Uses an infrared sensor (thermopile) to detect body temperature from the ear canal. Its operation is based on measuring the natural thermal radiation emanating from the tympanic membrane and the adjacent surfaces. The unit measures the infrared energy emitting from the middle ear and the surrounding tissue. This energy is absorbed by lenses and converted into temperature values	Uses an infrared sensor (thermopile) to detect body temperature from the ear canal. Its operation is based on measuring the natural thermal radiation emanating from the tympanic membrane and the adjacent surfaces. The unit measures the infrared energy emitting from the middle ear and the surrounding tissue. This energy is absorbed by lenses and converted into temperature values
Measurement location	Ear Canal	Ear canal

Probe cover needed?	Yes	No
Sensor type	MLX90615	TPS23B sensor
Lens Type	Transparent	Transparent
Measurement range	35.0- 42.0°C (95 -107.6 °F)	32.0- 42.2°C (89.6 -108.0 °F)
Display resolution	0.1°C or 0.1°F	0.1°C or 0.1°F
Temperature measurement accuracy	±0.2° C (35.0° C to 42°C), outside this range: High / Low	±0.3° C < 35.5° C, ±0.2° C (35.5° C - 42° C); ±0.3° C > 42° C
Position indicator	Yes(Application shows the usage)	Yes
Elevated Temperature Alarm	No	Yes (10 short beeps when measured temperature is greater than 37.5 °C)
Display an User Interaction	Requires an external device to display results and perform user interaction. Devices supported any Bluetooth enabled smart phone, tablet or personal computer RUNNING on Android OS version 4.0 and higher Or IOS OS version 7.0 or higher or Windows OS version 8.0 or higher	LCD display built in to the device
Communication	Wireless, based on Bluetooth V4.0 + EDR (Bluetooth Low energy)	Independent
Power Source	Rechargeable batteries (Li-Polymer3.7V, 850 mAh) and DC power 5V, 2A	2*AAA 1.5v alkaline battery
Operating Temperature and Humidity	10 to 40°C ((50.0°F~104.0°F) Atmospheric: 15 to 85% RH non-condensing	10.0°C - 40°C (50.0°F~104.0°F) with relative humidity 95%
Storage temperature and Humidity	-10 to 55° C Atmospheric**:** 15 to 85% RH non-condensing	-25°C to 55 °C/-13°F ~131°F with relative humidity 95%
Probe head: Tip Width	7.5mm	7.3mm
Probe head: Thickness at 5mm height	8.0mm	8.56mm
Probe head: Thickness at 10mm height	9.2mm	10.32mm

Material Make-up of the Device:

Comparison Item	Applicant	Predicate Device 1
IRT Probe cover	Polypropylene material	Polypropylene material
IRT Probe	ABS Plastic	ABS Plastic
Plastic material	ABS+PC Plastic	ABS Plastic

Summary with predicate device:

The principles of operations, core technology, the technological characteristics of patient contact materials, performance, biocompatibility function, mechanical safety, standards met, electrical safety, and EMC in the IRT temperature module of the B.O.L.T model VA01-1 are similar to the predicate device except the assembly and the implementation of the core design. A detailed document on the principles of operations, design, assembly and technology characteristics were submitted.

The device is similar to the predicate device in intended use, intended patient population, intended application site, working principle, contact material, resolution. Only their internal power supply, display range, communication and appearance differ and readout of the data/results where the B.O.L.T uses a wireless Bluetooth device to display the results and the predicate device has a built-in LCD display.

The material make up of the B.O.L.T IRT thermometer, model VA01-1 and the two predicate devices compared are similar and the exception is only in the color of the material.

AmZetta Technologies Private Limited believe that the B.O.L.T model VA01-1 patient monitor's IRT thermometer is substantially equivalent to the predicate devices.

Substantial Equivalence Comparison B.O.L.T Pulse Oximeter with Predicate Devices:

The B.O.L.T Pulse Oximeter model VA01-2 is compared with the following 510K approved devices:

K163135 – Fingertip Pulse Oximeter model A330, A310 from Shenzhen Fitfaith Technology Co.,Ltd

K140582 – Fingertip Pulse Oximeter JPD-500A from Shenzhen Jumper Medical Equipment Co.,Ltd

Comparison Item	Submitted proposed device	Predicate device 1	Predicate device 2
Applicant	AmZetta Technologies Private Limited.	Shenzhen Fitfaith Technology Co.,Ltd	Shenzhen Jumper Medical Equipment Co.,Ltd
Trade Name	B.O.L.T Pulse Oximeter	Fingertip Pulse Oximeter	Fingertip Pulse Oximeter
Model Name	B.O.L.T VA01-2	A330, A310	JPD-500A
510K Number	New Listing	K163135	K140582

Technological characteristics	Photoelectric Oxyhemoglobin Inspection Technology	Photoelectric Oxyhemoglobin Inspection Technology	Photoelectric Oxyhemoglobin Inspection Technology
Measuring method	A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO2) in red and near-infrared zones. Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, is shown on the connected Bluetooth device like a smartphone, tablet or personal computer display through process in electronic circuits and microcontroller of the base unit.	A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO2) in red and near-infrared zones. Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, is shown on the Oximeter's display through process in electronic circuits and microprocessor.	A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO2) in red and near-infrared zones. Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, is shown on the Oximeter's display through process in electronic circuits and microprocessor.

Sensor	Semiconductor gauge sensor	Semiconductor gauge sensor	Semiconductor gauge sensor
Light Specification			
Wavelength	660nm±3nm for red light,905nm±5nm for infrared light (IR)	660nm±3nm for red light, 905nm±5nm for infrared light (IR)	660nm±3nm for red light, 905nm±5nm for infrared light (IR)
Maximum optical power	1.5 mW for red light (660nm) 1.2 mW for IR (905nm)	1.5 mW for red light (660nm) 1.2 mW for IR (905nm)	1.5 mW for red light (660nm) 1.2 mW for IR (905nm)
Contact material	ABS+PC for enclosure, Silicone Rubber clip	ABS for enclosure, silica gel for clip	ABS for enclosure, silica gel for clip
Resolution			
SpO2	1%	1%	1%
Pulse rate	1 bpm	1 bpm	1 bpm
Measurement Range			
SpO2	0%~100%	0%~100%	0%~100%
Pulse rate	30~250 bpm	25~250 bpm	25~250 bpm
Measurement Accuracy			
SpO2	Arms ≤2.6%: (70%~100%) Unspecified: (0%~69%)	±2%: (70%~100%) Unspecified: (0%~69%)	±2%: (70%~100%) No definition: (0%~69%)
Pulse rate	±2 bpm	±2 bpm	±2 bpm
System Architecture	Requires the base unit B.O.L.T to connect to constitute a complete measurement system	Independent operation	Independent operation
Display an User Interaction	Requires an external device to display results and perform user interaction. Devices supported any Bluetooth enabled smart phone, tablet or personal computer running Android OS version 4.0 and higher Or iOS OS version 7.0 or higher or Windows OS version 8.0 or higher	LED display built in to the device	LED display built in to the device
Communication	Wireless, based on Bluetooth V4.0 + EDR (Bluetooth Low energy)	Independent	Independent

Power Source	Rechargeable batteries (Li-Polymer 3.7V, 850 mAh) and DC power 5V, 2A	2*AAA 1.5V alkaline battery	2*AAA 1.5V alkaline battery
Operating Temperature and Humidity	10 to 40℃ Atmospheric: 15 to 85% RH non-condensing	5℃~40℃ Atmospheric: 15%~85% noncondensing	5℃~40℃ Atmospheric: 15%~85% noncondensing
Storage Temperature and Humidity	-10 to 55℃ Atmospheric: 15 to 85% RH non-condensing	-20℃~+55℃ Atmospheric: 10%~95%	-10℃~+50℃ Atmospheric: 15%~93%

Material make-up of the device:

Comparison Item	Applicant	Predicate Device 1	Predicate Device 2
SPO2 Finger clip Material	Silicon rubber	Silicon Gel	Silicon Gel
Plastic Material for enclosure	ABS+PC Plastic	ABS Plastic	ABS Plastic

Summary with predicate device:

The principles of operations, core technology and the design used in the B.O.L.T Pulse oximeter, model VA01-2 Pulse oximeter are similar to the predicate device except the implementation design and the system architecture. A detailed design document on the principles of operations, design, assembly and technology characteristics were submitted.

The B.O.L.T pulse oximeter, model VA01-2 is similar to the predicate device in intended use, intended patient population, intended application site, working principle display range, resolution. Only their contact material, internal power supply, appearance differ and readout of the data/results where B.O.L.T uses a wireless Bluetooth connected devices to display the results and the predicate devices has a built-in display.

The B.O.L.T pulse oximeter, model VA01, VA01-2 and the predicate devices are substantially equivalent in the technological characteristics of patient contact materials, performance, biocompatibility function, mechanical safety, standards met, electrical safety, and EMC. The material make up of the B.O.L.T pulse oximeter, model VA01, VA01-2 and the two predicate devices compared are similar and the exception is only in the color of the material and B.O.L.T pulse oximeter uses Silicon rubber and the predicate devices use silicon gel.

AmZetta Technologies Private Limited believe that the B.O.L.T pulse oximeter model VA01, VA01-2 is substantially equivalent to the predicate devices.

Discussion of Clinical Tests performed:

B.O.L.T NIBP:

The B.O.L.T blood pressure monitor, model VA01-0 is compliant to the EN ISO 81060-2: 2014 Non-invasive sphygmommsnometers – Part 2: Clinical investigation of automated measurement type Standard for Manual, electronic, or automated sphygmomanometers. All the relevant activities were performed and the results demonstrated that the predetermined acceptance criteria were fully met.

106 subjects were recruited for the clinical study which included adult both male and female between 18 years and 65 years for Blood pressure and a total of 318 reading were taken for statistical analysis. For pulse rate statistical analysis 89 pulse rate reading was obtained. Omron model HEM 907 was used as the reference device. Omron IntellisenseTM Digital Blood Pressure Monitor, Model HEM-907 is approved under K032305.

The subject distribution was as per the EN ISO 81060-2:2014 Non-invasive sphygmommsnometers – Part 2: Clinical investigation of automated measurement type Standard for Manual, electronic, or automated sphygmomanometers standards.

The clinical study met the accuracy criteria as specified by EN ISO 81060-2:2014 standards. As per the Criterion I, mean error is 2.1 and 1.2 for Systolic Blood Pressure and Diastolic Blood Pressure respectively (falling within specified ISO criteria of less than 5). The standard deviation is 5.4 and 5.7 for Systolic Blood Pressure and Diastolic Blood Pressure respectively (falling within specified ISO criteria of less than 8). As per the Criterion 2, standard deviation for Systolic Blood Pressure is 4.39; and Diastolic Blood Pressure is 4.98 (Satisfied for both Systolic Blood Pressure (4.39 < 6.62) and Diastolic Blood Pressure (4.98 < 6.84).

The clinical study for Pulse rate accuracy based on the standard protocol specification. It is defined as ±5% from the reference device. 87 out of the 89 (97.75%) reading obtained for the study falls within the acceptance criteria. The detailed clinical study report was submitted.

B.O.L.T IRT Thermometer:

Controlled human clinical studies were conducted on the subject device, B.O.L.T IRT Thermometer, model VA01-1. Clinical protocol used for controlled human clinical studies and Clinical validation data is presented below.

IRT Temperature module of the B.O.L.T model VA01-1 patient monitoring system is compliant to the EN ISO 80601-2-56:2012 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. All the relevant activities were performed and the, results demonstrated that the predetermined acceptance criteria were fully met.

105 subjects were recruited for the clinical study which included adult both male and female between 18 years and 65 years. Of the 105 subjects, 37 were febrile subjects and 68 non-febrile subjects. A total of 105 reading were taken for statistical analysis. Braun PRO 4000 was used as the reference device. Braun ear thermometer, Model Pro 4000 is approved under K031928.

The clinical study for Body temperature met the accuracy criteria as specified by EN ISO 80601-2-56:2012 standards. As per the Criterion the Parameter Temperature Fahrenheit, the mean difference is -0.1 with mean bias of -0.10, standard deviation of 0.4 and limit of agreement of -0.86 to 0.66.

In addition, further clinical study were conducted as per ASTM E1965-98.

IRT Temperature module of the B.O.L.T model VA01-1 patient monitoring system is compliant to the ASTM E1965 − 98 (Reapproved 2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature. All the relevant activities were performed and the, results demonstrated that the predetermined acceptance criteria were fully met.

120 subjects were recruited for the clinical study which included adult both male and female between 18 years and 65 years. Of the 118 subjects, 35 were febrile subjects and 83 afebrile subjects. A total of 118 reading were taken for statistical analysis. Braun PRO 4000 was used as the reference device. Braun ear thermometer, Model Pro 4000 is approved under K031928. The DT-K11E was used as the contact reference thermometer is approved under K172861.

The clinical study for Body temperature met the accuracy criteria as specified by ASTM E1965-98 (reapproved 2016) standards. As per the Criterion the Parameter Temperature Fahrenheit, the clinical repeatability 0.1 with clinical bias of -0.008, standard deviation of 0.01 and limit of agreement of -0.26 to 0.25.

A detailed Clinical Study Report performed under EN ISO 80601-2-56:2012 standards and ASTM E1965-98 were submitted**.**

B.O.L.T Pulse Oximeter:

The B.O.L.T Pulse Oximeter model VA01-2 is compliant to the EN ISO 80601-2-61: 2011 - Medical electrical equipment - Part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment.

The purpose of the clinical trial was to evaluate the SpO2 accuracy performance of the B.O.L.T Fingertip Pulse Oximeter model VA01-2 during stationary (non-motion) conditions over a wide range. The Blood oxygen saturation (SpO2) accuracy are measured as per ISO 80601-2-61:2011, section EE.2.2: Invasive controlled de-saturation study on Patients. The SpO2 Accuracy of B.O.L.T BT4 are measured by comparing SpO2 readings to values obtained with that is traceable to Co-Oximeter SaO2 Values.

All the relevant activities were performed and the, results demonstrated that the predetermined acceptance criteria were fully met.

12 subjects were recruited and 10 Subjects were used for the clinical study which included adult both male and female between 18 years and 65 years. In the study there were 2 dark pigmented and 8 light pigmented subjects. For SpO2 functional oxygen saturation level clinical study, a total of 250 readings were taken for statistical analysis. For SpO2 pulse rate, statistical analysis 225 pulse rate readings were obtained using Electronic Pulse Simulator. Contec Medical Systems model CMS-50D (510K approval – K082641) was used as the reference device and Radiometer model ABL 800 Basic with Co-oximeter was used as the measuring SaO2 from arterial blood sample.

B.O.L.T Pulse Oximeter model VA01-2 controlled desaturation clinical study for functional oxygen saturation level (Sp02) met both the accuracy criteria as specified by EN ISO 80601-2-61:2011 - Medical electrical equipment - Part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment non-invasive method - induced controlled desaturation environment in healthy adults during non-motion conditions over the range of 70-100% SpO_2.

As per the standards, for the parameter Oxygen saturation (SpO2 %) A_{rms} value is 2.57. The mean difference is 2.49 with 95% confidence interval of (2.4, 2.6). For the parameter Pulse (In SpO2) A_{rms} value is 0.437. The mean difference is 0.067 with 95% confidence interval of (0.0108, 0.123).

A detailed Clinical Study Report performed were submitted

Non-Clinical Tests Performed:

Non-clinical tests were conducted to verify that the proposed device met all design specifications and to evaluate the safety and effectiveness. All the non-clinical test reports were submitted. The test results demonstrated that the proposed device complies with the standards. The standards are listed below

- IEC 60601-1:2005(Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 Medical devices Part1: General requirements for basic safety and essential performance Amendment 1, General requirements: Electrical Safety

- IEC 60601-1-11: 2015(Second Edition) Medical electrical equipment part 1-11: General requirements for basic safety and essential performance – Collateral Standard Requirement for medical equipment and medical electrical systems used in home healthcare environment - General Requirements: Electrical Safety

- ANSI/AAMI/IEC 60601-1-2: 2014 Medical electrical equipment part1-2: General requirements for basic safety and essential performance – Collateral standards: Electromagnetic compatibility – Requirements and tests, General requirements: EMC

- IEC 62304:2006(First Edition) + A1:2015 Medical device software: Software life-cycle processes - General requirements: Software

- IEC 60601-1-6:2010, AMD1:2013 Medical electrical equipment - Part 1 – 6: General Requirement for basic safety– Collateral Standard: Usability - General requirements: Usability

- ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process - Biological evaluation

- ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5 Tests for In Vitro Cytotoxicity - General Requirements: Biological estimation

- ISO 10993-10:2010 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity - General Requirements: Biological estimation

- ISO 13485 Medical devices- Quality management systems-Requirements for regulatory purposes - Quality Management Systems

- IEC 80601-2-30:2009/AMD1:2013 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers – General requirements: Essential performance

- EN ISO 80601-2-61:2011 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment - General requirements: Essential performance

- ISO 80601-2-56:2009 Medical electrical equipment — Part 2-56: Requirements for basic safety and essential performance of clinical thermometers for body temperature Measurement – Essential Performance

Biocompatibility Assessment:

Biocompatibility assessment was carried out for components in the devices where there is a surface contact to the body. Components tested were:

- *Plastics used in the devices. Plastic used in the device is ABS + Polycorbonate. There is a surface contact to the body and the duration is less than 1 minutes.*
- *NIBP Cuff Rubber Tube. There is a surface contact to the body and the duration is less than 5 minutes.*
- *NIBP Cuff. There is a surface contact to the body and the duration is less than 5 minutes*.
- *Pulse Oximeter (Spo2) Finger rubber. There is a surface contact to the body and the duration is less than 1 minutes*
- *IRT Probe cover. There is a surface contact to the body and the duration is less than 1 minutes.*

Following standards were used for the Biocompatibility assessment. The Biocompatibility assessment reports were submitted.

- *Invitro Cytotoxicity tests were carried as per the ISO 10993 – Part 5 standards.*
- *Intracutaneous reactivity test were carried as per the ISO 10993 – Part 10 standards.*
- *Skin Sensitization tests were performed as per the ISO 10993 – Part 10 standards.*

Shelf-life:

As there are no degradable components in the subject devices, shelf-life does not apply to the subject devices except the rechargeable battery. There are no time dependent parts used. The base unit has a rechargeable battery (Li-Polymer3.7V, 850 mAh) and DC power 5V, 2A. The rechargeable batteries usually has a shelf-life of 2-3 years and the batteries can be easily replaced**.**

Discussion on sterilization requirements:

There is no sterilization required. If required, the cuff can be wiped with a soft damp cloth.

Clean the rubber touching the finger inside the SpO2 probe gently by a soft cloth dampened with 70% isopropyl alcohol before measurement before each use.

There is no sterilization required for the B.O.L.T IRT Thermometer model VA01-1.

A new probe cover must be used for each measurement. Probe covers need to be disposed after the single use. Only the AmZetta provided/recommended Soft Touch cover must be used.

The user manual which is included in the device provides a detailed instruction on the care and maintenance of the device and the usage of the device.

Label and Labelling:

We have followed the standards of 21 CFR Part 801 as suggested by FDA and the following describes the proposed labelling.

The labelling is provided in the packaging. A user manual which is provided along with the system gives clear instructions on how to use the devices, the indications of use and any contra-indications. The user manuals also provide the proper usage of the devices and the maintenance of the devices.

Proposed labelling information and user manual were submitted.

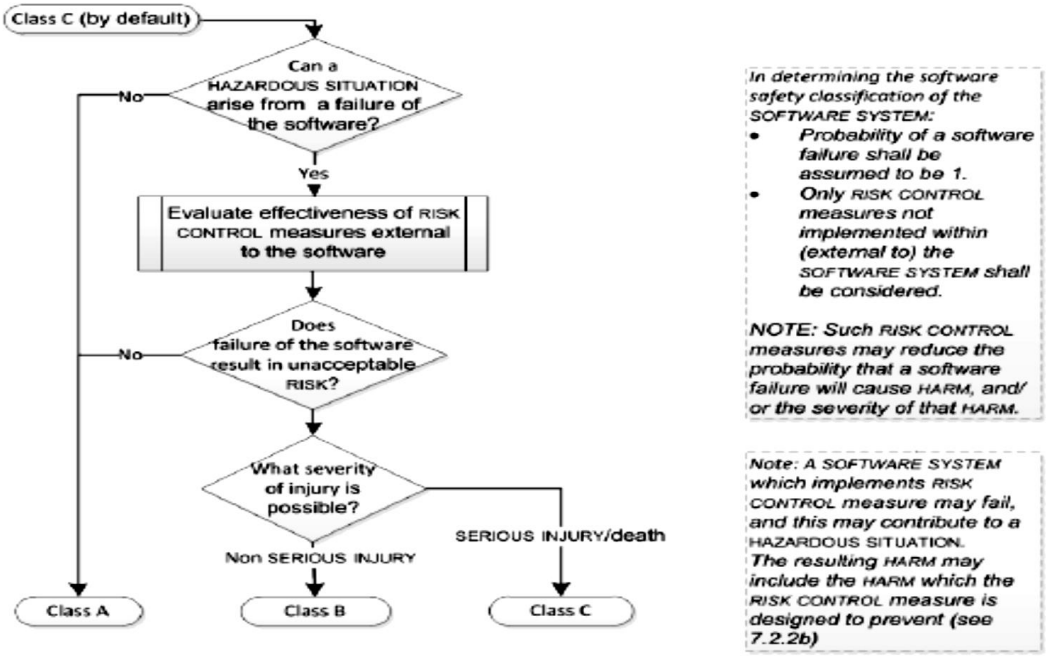
Software Development Methodology and Software Level of concern classification:

American Megatrends India Pvt Ltd is an ISO 13485 certified organization. The submission has undergone American Megatrends India Pvt Ltd's, design control, verification and validation testing. The validation testing includes testing of all executable code and functionality and confirmation that all identified risks have been adequately addressed by software functionality, the user interface, documentation and the User Guide.

We assign a software safety class (A, B, or C) to each software system according to the possible effects on the patient, operator, or other people resulting from a HAZARD (being a potential source of Harm) to which the software system can contribute. We assign the software safety classes to the medical device software application based on the severity as follows:

- **Class A:** No injury or damage to health is possible
- **Class B:** Non-SERIOUS INJURY is possible
- **Class C:** Death or SERIOUS INJURY is possible

The following flowchart provides the how software level of classification is derived at:



Software level of concern classification was done for the all the devices and the software level of concern was deemed **Class B (Moderate).**

The System verification and validation activities as part of the design control process include testing of all Design Specifications based on risk analysis and verification plans. American Megatrends India Pvt Ltd's test plan execution ensures each type of medical devices (NIBP, Spo2 and IRT) works with the base unit connectors for devices; and the base unit communication to the connected blue tooth device/s; and the SDK (Software Development Kit) to integrate the reading from the devices to an external system like a Care Portal/Electronic Medical Record software system. The output of these design control verification analysis documents meets its requirements and design specifications as intended.
Software verification and validation were performed internally and audited by an external agency for the company's software verification and validation protocol, procedures and policies. The audit reports from external audit were submitted.

510K Summary Conclusions:

We believe that technological characteristics, the operational characteristics, mode of operations, the performance and labelling information of the submitted B.O.L.T devices are similar to the predicate devices and systems currently in the market. The design of the submitted device specifications are substantially similar to the predicate devices.

The standards used for clinical and non-clinical tests are according to the standards recommended for the industry by FDA.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification AmZetta Technologies Private Limited. concludes that the B.O.L.T patient monitoring system, model VA01, VA01-0, VA01-1 and VA01-2 are substantially equivalent to predicate devices as described herein.