



December 23, 2019

Truly Instrument Limited
% Max Wong
Official Correspondent
Truly (U.S.A) Inc
2620 Concord Avenue, Suite 106
Alhambra, California 91803

Re: K192023

Trade/Device Name: Arm Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: November 29, 2019
Received: November 29, 2019

Dear Max Wong:

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 (for the indications for use stated in the enclosure) 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,

LT 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

Indications for Use

510(k) Number (if known)

K192023

Device Name

Arm Blood Pressure Monitor

Indications for Use (Describe)

Truly Automatic Arm Blood Pressure Monitor DB series, Models DB66-1, DB68 are a series devices intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.

The devices' features include irregular pulse rhythm detection during measurement, and will display a alert signal with the reading when irregular heartbeat is detected.

The devices' feature include Bluetooth function to transmit data to an external Bluetooth device with wireless communication

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

V1.0

Date of Summary Preparation: May 21.2019

1. Submitter's Identifications

Submitter's Name:	Truly Instrument Limited
Address:	Site 2, Truly Industrial Area, Shanwei City, Guangdong Province, China
Contact Person:	Manager Su-HaiSen
Telephone:	86-0660-3363561
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2. Name of the Device

Device Classification Name:	System, Measurement, Blood-Pressure, Non-invasive
Trade Nam:	Arm Blood Pressure Monitor
Models:	DB66-1, DB68
Classification Panel:	cardio-vascular
Common/Usual Name:	Automatic Arm Blood Pressure Monitor
Product Code:	DXN
Device Classification:	Class II
Contraindications :	N/A

3. The Predicate Devices

TRULY Instrument Limited.

Truly Automatic Arm Bluetooth Blood Pressure Monitor DB Series, Model DB62
510 K Number : K161846

4. Device Description

Automatic Arm Blood Pressure Monitor DB series, Models DB66-1, DB68 are designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well-known technique in the market called the "oscillometric method".

The main components of the Truly Automatic Arm Blood Pressure Monitor DB series are the main unit and cuff unit. ABS is used to outer housing of the main unit. The preformed cuff unit, which is applicable to arm circumference approximately between 220 and 340 mm, includes the inflatable bladder and nylon shell. All models of the arm blood pressure monitor use a single size of cuff. The device consists of the microprocessor, the pressure sensor, the operation keys, the pump, the electromagnetic deflation control valve and the LCD.

The devices also compares the longest and the shortest time intervals of detected pulse waves to mean time interval and displays a warning signal with the reading to indicate the detection of

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irregular pulse rhythm when the difference of the time intervals is over 25%.

The devices embed a Bluetooth 4.0 Wireless network connections module that allows it to connect to nearby receiving end. Once measurement is over, the LCD of device displays results, and the device will start to send out data such as systolic, diastolic, pulse, date, time with Wireless method and protocol.

5. Intended use of device

Automatic Arm Blood Pressure Monitor DB series, Models DB66-1, DB68 are a series devices intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.

The devices' features include irregular pulse rhythm detection during measurement, and will display a alert signal with the reading when irregular heartbeat is detected.

The devices' feature include Bluetooth function to transmit data to an external Bluetooth device with wireless communication .

6. Technological Characteristics of our new DEVICE COMPARED TO THE

PREDICATE DEVICE:

The technological characteristics of Automatic Arm Blood Pressure Monitor, models DB66-1, DB68 are substantially equivalent to Truly Automatic Arm Blood Pressure Monitor DB Series, Model DB62.(K161846). There is the same Owner, TRULY instrument Limited. Which FDA owner number is 9054344. In addition, there are the same design specifications, the same form and intended to be used in the same manner that means the new devices are same as the predicate devices.

Table-1: The comparison table

Parameter	Predicate Devices DB62	DB66-1	DB68	Explanation of the differences
Intended use	Measuring systolic and diastolic blood pressure and pulse rate of adult individual	Measuring systolic and diastolic blood pressure and pulse rate of adult individual		Identical
The trade name	Automatic Arm Bluetooth Blood Pressure Monitor	Arm Blood Pressure Monitor		Identical
510(K) Number	K161846			
Applicant	Truly Instrument Limited.	Truly Instrument Limited.		Identical
Regulatory Class	Class II	Class II		Identical
Panel	Cardiovascular	Cardiovascular		Identical
Product Code	DXN	DXN		Identical
Indications for use	Truly Automatic Arm Bluetooth Blood Pressure Monitor DB62 is intended to measure the systolic and diastolic blood	Truly Automatic Arm Bluetooth Blood Pressure Monitor DB62 is intended to measure the systolic and diastolic blood		Identical

Parameter	Predicate Devices DB62	DB66-1	DB68	Explanation of the differences
	<p>pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.</p> <p>The devices' features include irregular pulse rhythm detection during measurement, and will display a alert signal with the reading when irregular heartbeat is detected.</p> <p>The devices' feature include Bluetooth function to transmit data to an external Bluetooth device with wireless communication .. Over-The-Counter Use</p>	<p>pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.</p> <p>The devices' features include irregular pulse rhythm detection during measurement, and will display a alert signal with the reading when irregular heartbeat is detected.</p> <p>The devices' feature include Bluetooth function to transmit data to an external Bluetooth device with wireless communication .. Over-The-Counter Use</p>		
Target Population	Adult	Adult		Identical
Anatomical sites	Upper Arm	Upper Arm		Identical
Where used (hospital, home, ambulance. etc)	Home	Home		Identical
Energy used and / or delivered	4x 1.5V AA Battery	Polymer battery DC3.7V, 500mAh	4x 1.5V AA Battery	Equivalent The change in the specification is documented and tested,does not affect the intended use or the fundamental scientific technology.
Human factors	Blood pressure	Blood pressure		Identical
performance	Measuring systolic and diastolic blood pressure and pulse rate of adult individual, Including irregular pulse rhythm detection	Measuring systolic and diastolic blood pressure and pulse rate of adult individual, Including irregular pulse rhythm detection		Identical
biocompatibility	Cuff According to ISO-10993	Cuff According to ISO-10993		Identical
Compatibility with the environment and other devices	<p>Operation Environment: 10°C ~ 40°C, 15%~90%RH</p> <p>Storage Environment: -20°C ~ 60°C, 10%~95%RH</p> <p>Atmospheric: 70KPa~106KPa</p>	<p>Operation Environment: 10°C ~ 40°C, 15%~90%RH</p> <p>Storage Environment: -20°C ~60°C, 10%~95%RH</p> <p>Atmospheric: 70KPa~106KPa</p>		Identical

Parameter	Predicate Devices DB62	DB66-1	DB68	Explanation of the differences
Electrical safety	According to IEC60601-1-2 According to IEC60601-1	According to IEC60601-1-2 According to IEC60601-1		Identical
Sterilization	N/A	N/A		Identical
Chemical safety	N/A	N/A		Identical
sterility	N/A	N/A		Identical
Thermal safety	N/A	N/A		Identical
design	Refer to Table-2			
materials	Refer to Table-2			

Table-2: The comparison table in Design and Materials

Parameter	Predicate Devices DB62	DB66-1	DB68
Measurement algorithm Method	Oscillometric method	No change ,all same	No change ,all same
Measurement site of body	Arm	No change ,all same	No change ,all same
Max Cuff pressure	300mmHg	No change ,all same	No change ,all same
Bluetooth	BG312	H04J08C	
Irregular heartbeat detection	More than $\pm 25\%$ to the mean interval of pulse intervals. About the more detailed description of the IH detection algorithm, please refer to "Software validation report I-5. Algorithm description 4. Determination method of irregular heartbeat"..	No change ,all same	
Measurement Pressure Range	20 ~ 280 mmHg	No change ,all same	
Measurement Pulse Range	40 ~ 195 beats/min	No change ,all same	
Mesasuring resolution	1 mmHg	No change ,all same	
Accuracy Pressure	± 3 mmHg	No change ,all same	
Accuracy Pulse	$\pm 5\%$	No change ,all same	
Cuff Deflation	Automatic deflation	No change ,all same	
Pressurization Source	Automatic internal pump DC6V	Automatic internal pump DC3V	Automatic internal pump DC6V
Power Voltage	4X 1.5V	Polymer battery DC3.7V,500mAh	4x 1.5V AA Battery
Operating Environment	10~40°C, 15~90%RH	No change ,all same	
Storage Environment	-20°C ~ 60°C, 10%~95%RH		

Parameter	Predicate Devices DB62	DB66-1	DB68
Memory Size	4 x 99	99	99
Display Type	Liquid crystal display	Liquid crystal display ,Only difference size	
Cover		Difference	

7. Summary of Clinical study

Testing Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intend use. The following tests were performed on the device. Compliant to the standard of ISO 81060-2: Second Edition 2013-05-01 Non-invasive sphygmomanometers- Part 2: Clinical validation of automated measurement type. The results of this clinical investigation show that the required limits for mean difference and standard deviation are fulfilled by the subject device.

8. Non-Clinical Tests Performed:

8. Test Summary:

8-1. Electric Safety , EMC and FCC test reports.

General safety	IEC 60601-1:2005+A1:2012 Medical electrical equipment- Part1: General requirements for safety and essential performance
	IEC60601-1-11:2015 Medical electrical equipment-Part 1-11: General Requirement for basic safety and essential performance– Collateral Standard: Requirements for medical electrical systems used in the home healthcare environment
	EN60950-1:2013 Information technology equipment-Safety- Part1:General requirements
EMC conformity	IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General requirements for safety - collateral standard: Electromagnetic compatibility - Requirements and Tests
FCC conformity	FCC 47 part 15 subject B class B
ERM conformity	EN301489-1:2017;EN301489-17:2017
RF conformity	EN300328:2016
Health	EN62479:2010

8-2. Reliability & Clinical Test

IEC80601-2-30:20019 +A1:2013	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non – invasive sphygmomanometer
ISO 81060-2:2013	Non-invasive sphygmomanometers — Part 2: Clinical validation

	of automated measurement type
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8.3 Biocompatibility Test

ISO10993-1:2009	Biological evaluation of medical devices-Part 1: evaluation and testing
ISO10993-5:2009	Biological evaluation of medical devices-Part 5: Test for cytotoxicity in vitro methods
ISO10993-10:2010	Biological evaluation of medical devices-Part 10: Tests for irritation and sensitization

9. Conclusions

The new subject devices of Arm Blood Pressure Monitor continue to follow principles of hardware and software design of the predicate device DB62(K161846), and the feature, safety, effectiveness are also as same as DB62., Thus, the subject devices are substantially equivalent to the predicate devices.