



October 24, 2016

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

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

Re: K161846

Trade/Device Name: Automatic Arm Bluetooth Blood Pressure Monitor, with models  
DB62, DB63 and DB85

Regulation Number: 21 CFR 870.1130

Regulation Name: Noninvasive Blood Pressure Measurement System

Regulatory Class: Class II

Product Code: DXN

Dated: September 27, 2016

Received: October 4, 2016

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

**Indications for Use**

510(k) Number (if known)

K161846

Device Name

Automatic Arm Bluetooth Blood Pressure Monitor

Indications for Use (Describe)

Truly Automatic Arm Bluetooth Blood Pressure Monitor DB series, Models DB62, DB63, DB85 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.**

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# 510(k) Summary

V1.1

Date of Summary Preparation: Jan.16.2015

## 1. Submitter's Identifications

Submitter's Name:	Truly Instrument Limited
Address:	Site 2, Truly Industrial Area, Shanwei City, Guangdong Province, China
Contact Person:	Manager Yang Jian-Hao
Telephone:	86-0660-3380070
Fax:	86-0660-3380377

## 2. Name of the Device

Device Classification Name:	System, Measurement, Blood-Pressure, Non-invasive
Trade Name:	Automatic Arm Bluetooth Blood Pressure Monitor
Models:	DB62, DB63, DB85
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

### 3-1. YA HORNG Electronic Co., Ltd

Upper Arm Blood Pressure Monitor. Model BP-700NW and Bluetooth Transmission BP-700W.

K Number : K121025

### 3-2. TRULY Instrument Limited.

Truly Automatic Arm Blood Pressure Monitor DB Series, Model DB62M.

K Number :K091434

## 4. Device Description

Truly Automatic Arm Bluetooth Blood Pressure Monitor DB series, Models DB62, DB63, DB85 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

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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 subject devices are powered by four AA alkaline batteries.

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 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**

Truly Automatic Arm Bluetooth Blood Pressure Monitor DB series, Models DB62, DB63, DB85 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:**

6-1:The technological characteristics of Truly Automatic Arm Bluetooth Blood Pressure Monitor, models DB62, DB63, DB85 are substantially equivalent to Truly Automatic Arm Blood Pressure Monitor DB Series, Model DB62M.( K091434). There is the same Owner, TRULY instrument Limited. Which FDA owner number is 9055362. our new devices DB62. DB63, DB85 are the upgraded version to include the Bluetooth 4.0 Wireless function. 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-6-1: The comparison table**

Parameter	Predicate Devices DB62M(K091434)	DB62	DB63	DB85	Result
Indications for use	Measuring systolic and diastolic blood pressure and pulse rate of adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm., The devices features include	Truly Automatic Arm Bluetooth Blood Pressure Monitor DB series, Models DB62, DB63, DB85 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			Same

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Parameter	Predicate Devices DB62M(K091434)	DB62	DB63	DB85	Result
	irregular pulse nrhythm detection during measurement, and display a warning signal with the reading once the irregular heartbeat is detected. . Over-The-Counter Use	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 .. Over-The-Counter Use			
Target Population	Adult	Adult			Same
Anatomical sites	Upper Arm	Upper Arm			Same
Where used (hospital, home, ambulance, etc)	Home	Home			Same
Energy used and / or delivered	4x 1.5V AA Battery	4x 1.5V AA Battery			Same
Human factors	Blood pressure	Blood pressure			Same
Measurement algorithm Method	Oscillometric method	No change ,all same			Same
Cuff	No change ,all same According to ISO-10993				Same
Irregular heartbeat detection	More than $\pm 25\%$ to the mean interval of pulse intervals.				
Measurement Pressure Range	20 ~ 280 mmHg	No change ,all same			Same
Measurement Pulse Range	40 ~ 195 beats/min	No change ,all same			
Mesasuring resolution	1 mmHg	No change ,all same			
Accuracy Pressure	$\pm 3$ mmHg	No change ,all same			
Accuracy Pulse	$\pm 5\%$	No change ,all same			

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Parameter	Predicate Devices DB62M(K091434)	DB62	DB63	DB85	Result
PCB	1. The major PCB is all all same. 2. There is BLE module to direct connect to major PCB via the port RX and TX on the new Bluetooth models DB62,DB63,DB85.				
Software	Upgrade the software to include the data transmit with Uart protocol on the new Bluetooth models DB62, DB63, DB85.				
Compatibility with the environment and other devices	Operation Environment: 10°C~ 40°C, 15%~90%RH Storage Environment: -20°C~ 60°C, 10%~95%RH				Same
Electrical safety	According to IEC60601-1-2 According to IEC60601-1	According to IEC60601-1-2 According to IEC60601-1			Same
Mechanical safety	Same	Same			Same

6-2: Besides, the devices DB62, DB63, DB85 and the other predicate device YA HORNG Electronic Co., Ltd Upper Arm Blood Pressure Monitor. Model Bluetooth Transmission BP-700W( K121025) are also with the wireless communication function connect to an external Bluetooth enable device for data receiving and storage.

**Table-6-1: The comparison table**

Parameter	Predicate Devices BP-700W(K121025)	DB62	DB63	DB85	Result
Indications for use	The YA HORNG Upper Arm Blood Pressure Monitor, model BP-700NW and Bluetooth Transmission BP-700W are noninvasive blood pressure measurement systems intended to measure the systolic and diastolic blood pressures and pulse rate of an adult individual, over age 18, at home by using a non-invasive using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm, The cuff circumference is limited to be 9.0''~13.0'' for Arm type. Optional models: BP-700W with Bluetooth module for the wireless communication	Truly Automatic Arm Blood Pressure Monitor DB series, Models DB62, DB63, DB85 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 .  Over-The-Counter Use			Same

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Parameter	Predicate Devices BP-700W(K121025)	DB62	DB63	DB85	Result
	function connects to the PC for record archiving and printing purposes.  Over-The-Counter Use				
Target Population	Adult	Adult			Same
Anatomical sites	Upper Arm	Upper Arm			Same
Where used (hospital, home, ambulance, etc)	Home	Home			Same
Energy used and / or delivered	4x 1.5V AA Battery	4x 1.5V AA Battery			Same
Human factors	Blood pressure	Blood pressure			Same
Measurement algorithm Method	Oscillometric method	No change ,all same			Same
Cuff	Size: 9''~13'' (228mm~330mm) According to ISO-10993	Size: 220mm~340mm			Slightly different
Irregular heartbeat detection	More than $\pm 25\%$ to the mean interval of pulse intervals.				
Measurement Pressure Range	20 ~ 280 mmHg	No change ,all same			Same
Measurement Pulse Range	40 ~ 200 beats/min	40 ~ 195 beats/min			Slightly different
Mesasuring resolution	1 mmHg	No change ,all same			Same
Accuracy Pressure	$\pm 3$ mmHg	No change ,all same			Same
Accuracy Pulse	$\pm 5\%$	No change ,all same			Same
Electrical safety	According to IEC60601-1-2 According to IEC60601-1	According to IEC60601-1-2 According to IEC60601-1			Same

Parameter	Predicate Devices BP-700W(K121025)	DB62	DB63	DB85	Result
Mechanical safety	Same	Same			Same

## 7. Summary of Clinical study

### 1). Subjects:

Eighty-five subjects in the hospital were participated in clinical study.

### 2). Method:

A standard mercury sphygmomanometer was used as a reference standard. Simultaneous and blinded blood pressure determinations were performed by two doctors.

### 3). Criteria:

The ISO81060-2 Standard recommended :

A. a mean difference of  $\pm 5$  mmHg, with standard deviation of differences of  $\pm 8$  mmHg between test device and reference method.

B.

For the systolic and diastolic blood pressures for each of the  $m$  subjects, the standard deviation,  $s_m$ , of the averaged paired determinations per subject of the sphygmomanometer-under-test and of the reference sphygmomanometer shall meet the criteria listed in Tab 1 when calculated according to Equation(3).

**Table 1 — Averaged subject data acceptance (criterion 2)**

$\bar{x}_n$	Maximum permissible standard deviation, $s_m$ , as function of mean error, $\bar{x}_n$ mmHg									
	0,0	0,1	0,2	0,3	0,4	0,5	0,6	0,7	0,8	0,9
$\pm 0,$	6,95	6,95	6,95	6,95	6,93	6,92	6,91	6,90	6,89	6,88
$\pm 1,$	6,87	6,86	6,84	6,82	6,80	6,78	6,76	6,73	6,71	6,68
$\pm 2,$	6,65	6,62	6,58	6,55	6,51	6,47	6,43	6,39	6,34	6,30
$\pm 3,$	6,25	6,20	6,14	6,09	6,03	5,97	5,89	5,83	5,77	5,70
$\pm 4,$	5,64	5,56	5,49	5,41	5,33	5,25	5,16	5,08	5,01	4,90
$\pm 5,$	4,79	—	—	—	—	—	—	—	—	—

EXAMPLE For mean error of  $\pm 4,2$ , the maximum permissible standard deviation is 5,49.

### 4). Result

Through clinical research, we can convinced that the clinical device is safe and effective. The results of the clinical data refer the follow two tables.

	Criterion 1			Criterion 2	
	Diff(Systolic)	Diff (diastolic)		Diff(Systolic)	Diff (diastolic)
Mean	2.5mmHg	1.8mmHg	Mean	2.5mmHg	1.8mmHg
Std.	3.45mmHg	3.30mmHg	Std.	2.56mmHg	2.10mmHg

## 8. Test Summary:

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

General safety	IEC/EN 60601-1:2007
	IEC/EN60601-1-11
	EN60950-1:2011
EMC conformity	IEC/EN 60601-1-2:2010
FCC conformity	FCC 47 part 15 subject B class B
ERM conformity	EN30148-1:2008, EN30148-17:2009
RF conformity	EN300328:2006
Health	EN62479:2010

### 8-2. Performance & Clinical Test

ANSI/AAMI SP10:2002

ANSI/AAMI ISO 81060-2:2009

## 9. Conclusions

The new subject series devices of Truly Automatic Arm Bluetooth Blood Pressure Monitor continue to follow principles design of the predicate device DB62M(K091434), only upgraded to include the Bluetooth module . for the wireless communication function connects to an external Bluetooth enable device for data receiving and storage purposes . and the addition function Bluetooth substantially is equivalent to the predicate produce YA HORNG Electronic Co., Ltd Upper Arm Blood Pressure Monitor. Model Bluetooth Transmission BP-700W( K121025) .