November 21, 2017

Truly Instrument Ltd.
% Max Wong
Official Correspondent
Truly (U.S.A.) Inc.
2620 Concord Avenue
Suite 106
Alhambra, California 91801

Re: K170545
Trade/Device Name: Automatic Wrist Bluetooth Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: October 16, 2017
Received: October 18, 2017

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for 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

Indications for Use

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

510(k) Number *(if known)*
K170545

Device Name

Automatic Wrist Bluetooth Blood Pressure Monitor

Indications for Use *(Describe)*

Truly Automatic Wrist Bluetooth Blood Pressure Monitor DW702, DW703 are 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 wrist.

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

The devices' features 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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TRULY® Truly Instrument Limited

510(k) Summary

V1.0

Date of Summary Preparation: Jan.05.2017

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 Nam:	Automatic Wrist Bluetooth Blood Pressure Monitor
Models:	DW702,DW703
Classification Panel:	cardio-vascular
Common/Usual Name:	Automatic Wrist Blood Pressure Monitor
Product Code:	DXN
Device Classification:	Class Ⅱ
Contraindications :	N/A

3. The Predicate Devices

3-1. Truly Instrument.Limited

Automatic Wrist Blood Pressure Monitor Model: DW702M

K Number : K091415

3-2. Truly Instrument Limited.

Automatic Arm Bluetooth Blood Pressure Monitor DB Series, Model DB62

K Number : K161846

4. Device Description

Truly Automatic Wrist Bluetooth Blood Pressure Monitor DW702, DW703 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 wrist. 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 Wrist Blood Pressure Monitor Dw 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 Wrist circumference approximately between 135 and 220 mm, includes the inflatable bladder and nylon shell. All models of the Wrist 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 subject devices are powered by four AAA 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 Wrist Bluetooth Blood Pressure Monitor DW702 , DW703 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 Wrist.

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 Wrist Bluetooth Blood Pressure Monitor, models DW702 , DW703 are substantially equivalent to Truly Automatic Wrist Blood Pressure Monitor DB Series, Model DW702M.(K091415). There is the same Owner, TRULY instrument Limited. Which FDA owner number is 9055362. our new devices DW702, DW703 are the upgraded version to include the Bluetooth 4.0 Wireless function. In addition, there are the same dseign 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 DW702M(K091415)	DW702	DW703	Result
Indications for use	Measuring systolic and diastolic blood pressure and pulse rate of adult individual by using a non-incasive technique in which an inflatable cuff is wrapped around the Wrist ,The devices features include irregular pulse nrhythm detection during	Truly Automatic Wrist Bluetooth Blood Pressure Monitor DW702, DW703 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 Wrist. The devices' features include irregular pulse rhythm detection during measurement, and will display a alert signal with the reading when irregular heartbeat is detected.		Same

Parameter	Predicate Devices DW702M(K091415)	DW702	DW703	Result
	measurement, and display a warning signal with the reading once the irregular heartbeat is detected. . Over-The-Counter Use	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	Adult	Same
Anatomical sites	Wrist	Wrist	Wrist	Same
Where used (hospital, home, ambulance. etc)	Home	Home	Home	Same
Energy used and / or delivered	2x 1.5V AAA Battery	2x 1.5V AAA Battery	2x 1.5V AAA Battery	Same
Human factors	Blood pressure	Blood pressure	Blood pressure	Same
Measurement algorithm Method	Oscillometric method	No change ,all same	No change ,all same	Same
Cuff	No change ,all same According to ISO-10993			
Irregular heartbeat detection	More than ±25% to the mean interval of pulse intervals.			
Measurement Pressure Range	20 ~ 280 mmHg	No change ,all same	No change ,all same	Same
Measurement Pulse Range	40 ~ 195 beats/min	No change ,all same	No change ,all same	Same
Mesauring resolution	1 mmHg	No change ,all same	No change ,all same	Same
Accuracy Pressure	±3mmHg	No change ,all same	No change ,all same	Same
Accuracy Pulse	±5%	No change ,all same	No change ,all same	Same
PCB	1. The major PCB is all all same. There is BLE module to direct connect to major PCB via the port RX and TX on the new Bluetooth model DW702,DW703			
Software	Upgrade the software to include the data transmit with Uart protocol on the new Bluetooth model DW702. DW703			
Compatibility with the environment and other devices	Operation Environment: 10℃~ 40℃,15%~90%RH Storage Environment: -20℃~ 55℃,10%~95%RH			Same
Electrical safety	According to IEC60601-1-2 According to IEC60601-1 According to IEC60601-1-11			Same
Mechanical	Same	Same	Same	Same

Parameter	Predicate Devices DW702M(K091415)	DW702	DW703	Result
safety				

6-2: Besides, the devices DW702 ,DW703and the predicate device Automatic Arm Bluetooth Blood Pressure Monitor, Model DB62 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 DB62(K161846)	DW702	DW703	Result
Indications for use	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 . Over-The-Counter Use	Automatic Wrist Bluetooth Blood Pressure Monitor DW702,DW703 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 wrist. 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
Target Population	Adult	Adult	Adult	Same
Anatomical sites	Upper Arm	wrist	wrist	Same
Where used (hospital, home, ambulance.	Home	Home	Home	Same

Parameter	Predicate Devices DB62(K161846)	DW702	DW703	Result
etc)				
Energy used and / or delivered	4x 1.5V AA Battery	2x 1.5V AAA Battery	2x 1.5V AAA Battery	Same
Human factors	Blood pressure	Blood pressure	Blood pressure	Same
Measurement algorithm Method	Oscillometric method	No change ,all same	No change ,all same	Same
Cuff	Size: 220mm~340mm According to ISO-10993	Size: 135mm~220mm According to ISO-10993		Slightly different
Irregular heartbeat detection	More than ±25% to the mean interval of pulse intervals.			
Measurement Pressure Range	20 ~ 280 mmHg	No change ,all same	No change ,all same	Same
Measurement Pulse Range	40 ~ 195 beats/min	40 ~ 195 beats/min	40 ~ 195 beats/min	Slightly different
Mesauring resolution	1 mmHg	No change ,all same	No change ,all same	Same
Accuracy Pressure	±3mmHg	No change ,all same	No change ,all same	Same
Accuracy Pulse	±5%	No change ,all same	No change ,all same	Same
Electrical safety	According to IEC60601-1-2 According to IEC60601-1 According to IEC60601-1-11			Same
Mechanical safety	Same	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 x5mmHg, with standard deviation of differences of x8 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
± 0,	6,95	6,95	6,95	6,95	6,93	6,92	6,91	6,90	6,89	6,88
± 1,	6,87	6,86	6,84	6,82	6,80	6,78	6,76	6,73	6,71	6,68
± 2,	6,65	6,62	6,58	6,55	6,51	6,47	6,43	6,39	6,34	6,30
± 3,	6,25	6,20	6,14	6,09	6,03	5,97	5,89	5,83	5,77	5,70
± 4,	5,64	5,56	5,49	5,41	5,33	5,25	5,16	5,08	5,01	4,90
± 5,	4,79	—	—	—	—	—	—	—	—	—
EXAMPLE For mean error of ± 4,2, the maximum permissible standard deviation is 5,49.										

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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	-2.8mmHg	-2.9mmHg		Std	4.27mmHg	4.16mmHg
Std.	5.0mmHg	4.8mmHg		**Criteria in the Table 1**	6.34mmHg	6.30mmHg

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	EN300328:2015
Health	EN62479:2010

8-2. Performance & Clinical Test

ANSI/AAMI SP10:2002

ANSI/AAMI ISO 81060-2:2009

9. Conclusions

The new subject devices of Truly Automatic Wrist Bluetooth Blood Pressure Monitor continue to follow principles design of the predicate device DW702M (K091415), 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 Truly Automatic Arm Bluetooth Blood Pressure Monitor DB62(K161846)。