510(k) Summary

SEP - 4 2009

Date of Summary Preparation: 4.20.2009

1. Submitter's Identifications

Submitter's Name: Truly Instrument Limited
Address: Truly Industrial Area, Shanwei City, Guangdong Province, China
Contact Person: Manager Yang Jian-Hao
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2. Name of the Device

Device Classification Name: System, Measurement, Blood-Pressure, Non-invasive
Models: DB21, DB22, DB23, DB31, DB32, DB61M, DB62M, DB63M, DB71M
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

a. Digibio Digital Blood Pressure Monitor, Model D11, K014141
b. Microlife Blood Pressure Monitor, Model BP3BT0-AP, K041411

4. Device Description

Truly Automatic Arm Blood Pressure Monitor DB series, Models DB21, DB22, DB23, DB31, DB32, DB61M, DB62M, DB63M, DB71M 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 subject devices are powered by four AAA or AA alkaline batteries.
The device 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%.

5. Intended use of device

Truly Automatic Arm Blood Pressure Monitor DB series, Models DB21, DB22, DB23, DB31, DB32, DB61M, DB62M, DB63M, DB71M 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 display a warning signal with the reading once the irregular heartbeat is detected.

6. Summary of Substantial Equivalence

Table 1: The difference between Truly Automatic Arm Blood Pressure Monitor DB series and Digibio Digital Blood Pressure Monitor, Model D11.

Parameter	Predicate Devices D11	DB 21	DB 22	DB 23	DB 31	DB 32	DB 61M	DB 62M	DB 63M	DB 71M
Measurement algorithm Method	Oscillometric method	No change ,all same								
Measurement site of body	Arm	No change ,all same								
Pressure Sensor	MSP-2107	No change ,all same								
Cuff		No change ,all same								
Software		D11 software + Irregular heartbeat detection.								
Irregular heartbeat detection		More than ±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". DB22, DB23, DB61M, DB62M, DB63M, DB71M have the IH feature.								
Memory Size	2 x 60	2X60	2X50	4X99	2X60	1X99	4X99	4X99	4X99	4X99
Measurement Pressure Range	20 ~ 280 mmHg	No change ,all same								
Measurement Pulse Range	40 ~ 195 beats/min	No change ,all same								

Parameter	Predicate Devices D11	DB 21	DB 22	DB 23	DB 31	DB 32	DB 61M	DB 62M	DB 63M	DB 71M
Mesauring resolution	1 mmHg	No change ,all same								
Accuracy Pressure	±3mmHg	No change ,all same								
Accuracy Pulse	±5%	No change ,all same								
Pressurization Source	Automatic internal pump	No change ,all same								
Ciff Deflation	Automatic deflation	No change ,all same								
Operating Environment	10~40℃ 15~90%RH	No change ,all same								
Power Vovtage	4X 1.5V	No change ,all same								
Hardware circuit		No change ,all same								
Electronic element		No change ,all same								
PCB		Only DB22 PCB is solely ,other PCB of model DB21/23/31/32/61M/62M/63M/71M are same to D11								
Display Type	Liquid crystal display	No change ,all same								
Cover		Difference								

Table 2: The difference between Truly Automatic Arm Blood Pressure Monitor DB series and Microlife Blood Pressure Monitor, Model BP3BT0-AP.

Parameter	Predicate Devices BP3BT0-AP	DB 21	DB 22	DB 23	DB 31	DB 32	DB 61M	DB 62M	DB 63M	DB 71M
Measurement Method	Oscillometric Method	No change - the same								
Pressure Sensor	Capacitive	No change - the same								
Measurement Range:BP	30~280mmHg	20 ~ 280 mmHg								
Measurement Range:BP	40~200 beats/min	40 ~ 195 beats/min								
Mesauring resolution	1mmHg	No change - the same								

Parameter	Predicate Devices / BP3BT0-AP	DB 21	DB 22	DB 23	DB 31	DB 32	DB 61M	DB 62M	DB 63M	DB 71M
Accuracy Pressure	±3mmHg	No change - the same								
Accuracy Pulse	±5%	No change - the same								
Pressurization Source	Automatic internal pump	No change - the same								
Ciff Deflation	Automatic deflation	No change - the same								
Memory Size	99	2X60	2X50	4X99	2X60	1X99	4X99	4X99	4X99	4X99
Irregular Heartbeat Detection	More than ±25% to the mean interval of pulse intervals	DB22, DB23, DB61M, DB62M, DB63M, DB71M have the IH feature.								
Power Source	4 X1.5V	No change - the same								
Operating Environment	10~40℃ 15~90%RH	No change - the same								
Cuff Attachment Method	By plastic hose connected to monitor	No change - the same								
Display Type	Liquid crystal display	Liquid crystal display								

7. Conclusions

The subject devices have all features of the predicate device D11 except the new features such as irregular heartbeat detection. These differences do not affect the safety and effectiveness of the subject devices.

Irregular heartbeat detection technology is same as what is used Microlife Blood Pressure Monitor, Model BP3BT0-AP, K041411

Thus, the subject devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

SEP - 4 2009

Truly Instrument Co., Ltd.
c/o Mr. Yang Jian-Hao
Manager
Truly Industrial Area
Shanwei, Guangdong 516600
China

Re: K091434
Trade/Device Name: Truly Automatic Arm Blood Pressure Monitor Models DB21, DB22, DB23, DB31, DB32, DB61M, DB62M, DB63M and DB71M.
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: Undated
Received: August 7, 2009

Dear Mr. Yang:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091434

TRULY®

Truly Instrument Limited

Indication for Use

510(k) Number (if known):

Device Name: Truly Automatic Arm Blood Pressure Monitor DB Series,
Models DB21,DB22,DB23,DB31,DB32,DB61M,DB62M,DB63M,DB71M

Indication For Use:

Truly Automatic Arm Blood Pressure Monitor ,Models DB21, DB22, DB23, DB31, DB32, DB61M, DB62M, DB63M, DB71M 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 display a warning signal with the reading once the irregular heartbeat is detected.

Prescription Use _____ And Over the Counter Use ___X___.

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K091434

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