MAR - 1 2012

REMARKET NOTIFICATION

510(k) SUMMARY

(As Required By 21 CFR 807.92)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K113238 Date: NOV 01 2011

1. Submitter:

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2. Name of the Device:

Trade Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL888HD
Common Name: Blood Pressure Monitor
Classification Name: Non-invasive Blood Pressure Measurement System
Classification: Class II, 21CFR 870.1130
Classification Panel: Cardiovascular
Product Code: DXN

3. Information for the 510(k) Cleared Device (Predicate Device):

A. Full Automatic (NIBP) Blood Pressure Monitor, Model HL868BF, K092161
B. A&D Medical UA-767PBT Digital Blood Pressure Monitor, K043217

4. Device Description:

HL888HD automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method. All values can be read out in one LCD panel. Measurement position is at human being's upper arm. The intended use of this over-the-counter device is for use by people over the age of 18 with arm circumference ranging from approx. 9 inches to 17 inches (23 cm to 43 cm) and for home use.

The user is able to set the personal target values for blood pressure self-management. When the user's blood pressure readings exceed the self management pressure level, a RED LCD backlight of either systolic/diastolic or both will illuminate. If the readings are equal or lower than the preset values, the screen will illuminate BLUE LCD backlight.

User's measuring results can be automatically transmitted to the paired Bluetooth device via the built-in Bluetooth module once measurement completed.

5. Intended Use

HL888HD automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method. All values can be read out in one LCD panel. Measurement position is at human being's upper arm.

The intended use of this over-the-counter device is for use by people over the age of 18 with arm circumference ranging from approx.9 inches to 17 inches (23 cm to 43 cm) and for home use.

6. Comparison of device to predicate device:

Product Specification Comparison Table of Subject device HL888HD and predicate device HL868BF (K092161)

Item	Subject device HL888HD	Predicate device HL868BF (K092161)
Method of measurement	Oscillimetric	Oscillimetric
Range of measurement	Pressure 0- 300mmHg, Pulse 40-199 Beats/minute	Pressure 0- 300mmHg, Pulse 40-199 Beats/minute
Accuracy	Pressure +/− 3mmHg Pulse +/− 5%	Pressure +/− 3mmHg Pulse +/− 5%
Inflation	Automatic inflation (Air pump)	Automatic inflation (Air pump)
Deflation	Automatic air release control valve	Automatic air release control valve
Exhaust	Automatic exhaust valve	Automatic exhaust valve
Display	Liquid Crystal Digital Display	Liquid Crystal Digital Display
Power Supply	6V DC, 4 × "AA" (1.5V) Alkaline batteries	6V DC , 4 × "AA" (1.5V) Alkaline batteries or AC adapter (optional)
Storage/	- 20℃ ~ + 70℃	- 20℃ ~ + 70℃

Transportation Temperature	(- 4°F~ +158°F), ≦ 90%RH	(- 4°F~ +158°F), ≦ 90%RH
Operating Temperature	10℃ ~ 40℃ (50°F~104°F), 15% ~ 90%RH	10℃ ~ 40℃ (50°F~104°F), 15% ~ 90%RH
Material	ABS housing and ABS keys	ABS housing and rubber keys
Sets of memory	1*99	3*80, total 240
Number of Push Bottom	4	5
Storage pouch	Yes	Yes
Cuff size	Arm circumference approx. 23-43 mm(9~17 inches)	Arm circumference approx. 23-43 mm(9~17 inches)
Unit Weight	9.93 ± 0.35 oz (281.5 ± 10 g) (Cuff and Batteries excluded)	Approx. 17.5 oz (including batteries)

Changes from the predicate device HL868BF (K092161):

*Changing of numbers of push buttons', push buttons' positions, exterior casing design and color

* Modify Personal Target Limits with BLUE/RED LCD backlight instead of SMILING symbol and flash on the screen

*Additional product feature of Bluetooth Data Transmission Function

For the product feature of Bluetooth data transmission, was compared with the other predicate device A&D UA-767PBT (K043217).

7. Discussion of Clinical Tests Performed:

Subject device HL888HD is compliant to the ANSI/AAMI SP10:2002/(R) 2008 & ANSI/AAMI SP10:2002 /A1:2003/(R) 2008 & ANSI/AAMI SP10:2002/ A2:2006/(R) 2008 Manual, electronic or automated sphygmomanometers Standard for Manual, electronic, or automated sphygmomanometers. All the relevant activities were performed by designate individual(s) and the results demonstrated that the predetermined acceptance criteria were fully met.

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The subject device was tested to evaluate its safety and effectiveness, including the followings:

a. Safety Test: IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

b. EMC Test: IEC 60601-1-2 Edition 3:2007-03, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

c.FCC Test: FCC 47 CFR Part 15, Subpart B

d. Biocompatibility Test:

- ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.
- ISO 10993-10:2002/Amd. 1:2006(E), Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity amendment 1.

e. Reliability Test: ANSI/AAMI SP10:2002/(R) 2008 & ANSI/AAMI SP10:2002/A1:2003/(R) 2008 & ANSI/AAMI SP10:2002/A2:2006/(R) 2008, Manual, electronic or automated sphygmomanometers.

f. Risk Assessment: ISO 14971:2007 Medical devices – Application of usability engineering to medical device.

9. Conclusions:

The subject device was tested and fulfilled the requirements from those standards mentioned above, and it's concluded that the subject device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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MAR - 1 2012

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Taiwan

Re: K113238
Trade/Device Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL888HD
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: February 23, 2012
Received: February 27, 2012

Dear Ms. Su:

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.
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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,

M-J. Hillebrenner

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

Enclosure

Indication for Use

510(k) Number (if known): K113238

Device Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL888HD

Indications for Use:

HL888HD automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method. All values can be read out in one LCD panel. Measurement position is at human being's upper arm.
The intended use of this over-the-counter device is for use by people over the age of 18 with arm circumference ranging from approx.9 inches to 17 inches (23 cm to 43 cm) and for home use.

HL888HD features a built-in "Bluetooth Data Transmission" function, which enables the device automatically transmit measuring results to paired Bluetooth device after measurement.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __V__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Devices Evaluation (ODE)

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M.A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

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