DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 03, 2017

A&D Company, Ltd
% Jerry Wang
Director of Engineering
1756 Automation Parkway
San Jose, California 95131

Re: K163683
Trade/Device Name: A&D Medical UA-1200BLE Ultraconnect Digital Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: March 31, 2017
Received: April 3, 2017

Dear Jerry Wang:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163683

Device Name

UA-1200BLE UltraConnect Digital Blood Pressure Monitor

Indications for Use *(Describe)*

Measure blood pressure (systolic and diastolic) and pulse rate.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This summary of 510(k) safety and effective information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1. Date Prepared

December 23, 2016

2. Submitter's Information

A&D Engineering, Inc.
Mr. Jerry Wang
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3. Device Information

Proprietary Name:	A&D Medical UA-1200BLE UltraConnect Digital Blood Pressure Monitor
Regulation Number:	21 CFR 870.1130
Regulation Name:	Noninvasive Blood Pressure Measurement System
Regulatory Class:	Class II
Product Code:	DNX

4. Information for he 510(k) Cleared Devices (Predicate Devices)

- A&D Medical UA-651 Digital Blood Pressure Monitor with 510(k) number K141160
- A&D Medical UA-767PBT Digital Blood Pressure Monitor with 510(k) number K043217

Both predicate devices are designed and manufactured by the same company and facilities as the modified device.

5. Indications for Use

Measure blood pressure (systolic and diastolic) and pulse rate

6. Intended Use

A&D LifeSource UA-1200BLE digital blood pressure monitor is designed for adult at home or clinic use. It measures systolic, diastolic, and pulse rate. UA-1200BLE uses the oscillometric method to determine blood pressure. If the user has a massive body movement or irregular heartbeats, a heart symbol will be shown on the app display. At the end of the measurement, the blood pressure results are compared with JNC VII hypertension classification. The rating is also displayed. UA-1200BLE has *Bluetooth*® low energy wireless (BLE) communication capability with Smart devices. UA-1200BLE fits arm size from 22 to 42 cm.

7. Device Description – Technological and Operational Characteristics Comparison

UA-1200BLE of digital blood pressure monitor has the same design as the predicate devices with an inflatable cuff which is wrapped around the patient's upper arm. After the user starts the blood pressure measurement, the cuff is inflated automatically by an internal pump. The systolic

and diastolic blood pressures are also determined by oscillometric method. The deflation rate is controlled by an internal exhaust valve. There is a quick exhaust mechanism so that the cuff pressure can be completely released immediately. There is a maximum pressure safety setting at 299 mmHg. UA-1200BLE UltraConnect Digital Blood Pressure Monitor will not inflate the cuff higher than 299 mmHg. UA-1200BLE will turn on an irregular heartbeat indicator if an irregular heartbeat was detected during the measurement process. At the end of the measurement, the systolic and diastolic pressures with pulse rate are shown on the OLED and transmitted via Bluetooth wireless module to the connected app. The cuff is also deflated automatically to 0 mmHg at the same time. If the monitor receives no further action from the user for 1 minute, it will automatically turn off by itself.

8. Summary of Substantial Equivalence

Modifications made from the predicate devices:

- Remove the plastic host between the cuff and main BP monitor. Basically, UA-1200BLE is a hoseless BP monitor comparing with the predicate devices. We also changed the plastic molds so the UA-1200BLE digital blood pressure monitors have a new appearance.
- Enable user ID so up to six users can use the UA-1200BLE.
- Increase the memory size to 100 per user except in the visitor mode.
- Change upper limit of the arm size from 17.7 inches (45 cm) to 16.5 inches (42 cm).
- Change pressure sensor from static electricity capacity type to semiconductor type

Product Specification Comparison Table:

Model	Predicate Devices		Modified Device
	UA-767PBT	**UA-651**	**UA-1200BLE**
Measurement Method	Oscillometric Method	Oscillometric Method	No change
Measurement Range	BP : 20 - 280mmHg Pulse : 40 - 200beats per minute	BP : 0 - 299mmHg Pulse : 40 - 180beats per minute	No change from UA-651
Measurement Accuracy	BP : +/- 3mmHg or +/- 2% of measured value, whichever is greater Pulse :+/- 5%(pulse)	BP : +/- 3mmHg Pulse :+/- 5%(pulse)	No change from UA-651
Minimum Display Resolution	1 mmHg	1 mmHg	No change
Pressure sensor	Static electricity capacity type sensor	Static electricity capacity type sensor	Semiconducting type sensor
Pressurization Source	Automatic internal pump	Automatic internal pump	No change
Cuff Deflation Method	Automatic constant speed mechanical exhaust valve	Automatic constant speed mechanical exhaust valve	Solenoid valve for rapid exhaust
Display Type	Liquid crystal display	Liquid crystal display	OLED display
Cuff Attachment Method	By plastic hose connected to monitor	By plastic hose connected to monitor	Integrated (hoseless)

IHB	Enabled	Enabled	No change
%IHB	No	Enabled. %IHB is displayed as frequency of IHB detected	No change from UA-651
Power Source	6V DC, 4x1.5V AA batteries or AC adaptor as an option	6V DC, 4x1.5V AA batteries or AC adaptor as an option	3.7V Li-ion batteries or AC adaptor as an option
Protection against electrical shock	Class I, Type B	Class I, Type B	No change
Battery Life	6 months with one measurement dairy	6 months with one measurement dairy	3 months with one measurement daily
Operating Environment	50°F(10°C) to 104°F(40°C) at less than 85%RH	50°F(10°C) to 104°F(40°C) 15%RH to 85%RH	No change
Storage Environment	-4°F(-20°C) to 140°F(60°C) at less than 85%RH	-4°F(-20°C) to 140°F(60°C) 10%RH to 95%RH	No change
Data Memory Size	Last 40 measurements of systolic, diastolic, and pulse rate	Last 60 measurements for each of the four user	Last 100 measurements for each of the five user
Dimensions	163.7(H)x111(W)x66.7(L) mm	140(W)x60(H)x105(D) mm	40(W)x126(H)x26(D) mm
Weight	320g without batteries	255g without batteries	205g without batteries
Cuff Design	D-ring cuff with plastic hose	D-ring cuff with plastic hose	D-ring cuff(Integrated) Hoseless
Arm Size	13 to 45 cm	22 to 45 cm	22 to 42 cm
Clock (Time/Date)	Yes (By App)	Yes	No change from UA-767PBT
AM/PM	No	Yes	No change from UA-651
Pressure Indicator	Yes	Yes	No change
Wireless Radio Connectivity	Bluetooth wireless	No	No change from UA-767PBT
Field service	Not allowed	Not allowed	No change
Automatic Zero at "START"	Yes	Yes	No change
Manual Zero Adjustment	Not allowed	Not allowed	No change

Calibration	Not allowed in the field	Not allowed in the field	No change
Sterilization	Not needed	Not needed	No change
Blood Pressure Reading Classification Criteria	USA JNC Ⅶ	WHO Classification Criteria	No change from UA-767PBT

Key Features Comparison

Parameter	**Predicate Devices (UA-651 & UA-767PBT**	**Modified Device (UA-1200BLE)**
Field service	Not allowed	No change – the same
Automatic zero after "START" operation	Yes	No change – the same
Manual zero adjustment	Not allowed	No change – the same
Calibration	Not allowed in the field	No change – the same
Sterilization	Not needed	No change – the same

9. **Discussion of standards used in the design verification and design validation**

A&D Medical follows FDA recognized consensus standards and guidance documents in our medical device development and manufacturing processes. The following standards were used to for the design verification and valuation of UA-1200BLE UltraConnect Digital Blood Pressure Monitor. These standards include three major groups. First group is the general quality system requirements. Second group is the special requirements for CDRH (870.1130). The third group is related to software and app life cycle processes requirements.

- AAMI/ANSI/ISO 14971:2007/(R) 2010 (Corrected 4 October 2007)
  Medical Devices - Applications Of Risk Management To Medical Devices (FDA Recognized Number 5-70)

- IEC 60601-1-11 Edition 1.0 2010-04
  Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment [Including: Technical Corrigendum 1 (2011)] (FDA Recognized Number 19-6)

- 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 (FDA Recognized Number 19-1)

- AAMI/ANSI/IEC 60601-1-2:2007/(R)2012
  Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests (Edition 3) (FDA Recognized Number 19-2)

- AAMI/ANSI/ISO 81060-2 Second Edition 2013-05-01
  Non-Invasive Sphygmomanometers - Part 2: Clinical Validation Of Automated Measurement Type (FDA Recognized Number 3-117)

- AAMI/ANSI/IEC 80601-2-30:2009 & A1:2013
  Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Noninvasive Sphygmomanometers (FDA Recognized Number 3-130)

- AAMI/ANSI/IEC 62304:2006
  Medical Device Software - Software Life Cycle Processes (FDA Recognized Number 13-32)

10. Substantial Equivalence Conclusion:

Non-clinical Test Summary:

- Safety Tests: IEC 60601-11 Edition 1.0 2010-04
- EMC Tests: IEC 60601-1-2 Edition 3: 2007-03
- Reliability Tests: ASMI/ANSI/IEC 80601-2-30:2009 & A1:2013
- Risk Assessment: ISO 14971:2012
- Software Assessment: IEC Medical Life Cycle Process & FDA "Guidance for the Content of Premarket Submissions for Software contained in Medical Devices", November 2005.
- Bluetooth Tests: FCC Part 15 Subpart C : 2014

Clinical Test Summary based on AAMI/ANSI/ISO 81060-2 Second Edition 2013-05-01

Item	Standard Requirements	Study Results		Pass/Fail
Number of Subject	85 or more	85	100%	Pass
Number of Measurement	3 times or more	3 times	100%	Pass
Observer	2	2	100%	Pass
Observer Difference	+/- 4 mmHg or less	+/- 4 mmHg less	100%	Pass
Gender	Male 30% or more	59	69.4%	Pass
	Female 40% or more	26	30.6%	Pass
Age	Older than 12 years : 100%	85	100.0%	Pass
Circumference of Arm	22.0 – 32.0 cm : 40% or more	49	57.6%	Pass
	32.1 – 42.0 cm : 40% or more	36	42.4%	Pass
	22.0 – 27.0 cm : 20% or more	28	32.9%	Pass
	37.0 – 42.0 cm : 20% or more	17	20.0%	Pass
BP Range	SBP<100mmHg 5% or more	19	7.5%	Pass
	SBP>160mmHg 5% or more	15	5.9%	Pass
	SBP<140mmHg 20% or more	51	20.0%	Pass
	DBP<60mmHg 5% or more	19	8.2%	Pass
	DBP>100mmHg 5% or more	23	9.0%	Pass
	DBP >85mmHg 20% or more	87	34.1%	Pass
Measurement Result	Average : +/-5mmHg or less	SBP	-2.66mmHg	Pass
		DBP	+0.90mmHg	Pass
	S.D. : 8mmHg or less (Criteria 1)	SBP	6.90mmHg	Pass
		DBP	6.63mmHg	Pass

	S.D. : 8 mmHg or less (Criteria 2)	SBP	5.35 mmHg	Pass
		DBP	6.12 mmHg	Pass

UA-1200BLE of digital blood pressure monitors Digital blood pressure monitors have the following similarities to the predicate devices, UA-651 and UA-767PBT digital blood pressure monitors, which previously received the 510(k) clearance.

- Same intended use.
- Same oscillometric method to determine the blood pressure & pulse rate
- Same inflation method – automatic internal pump
- Same fast safety deflation method – solenoid controlled exhaust valve
- Same materials, no new materials used
- Same manufacturing processes at the same facility
- Same Indications For Use

As a conclusion, UA-1200BLE UltraConnect digital blood pressure monitor as described in its labeling and comparison analysis has not changed as a result of the modifications. The fundamental scientific technology of the modified device has not changed, either. There is no significant difference that affects the safety or effectiveness of the modified device as compared to the predicate devices.