October 6, 2022

A&D Company, Ltd
Chanda Melville
Quality Manager
1756 Automation Parkway
San Jose, California 95131

Re: K212168
Trade/Device Name: A&D Medical UM-212BLE Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: August 22, 2022
Received: September 6, 2022

Dear Chanda Melville:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212168

Device Name
A&D Medical UM-212BLE Blood Pressure Monitor

Indications for Use *(Describe)*
UM-212BLE blood pressure monitor is designed to measure systolic, diastolic pressure, and pulse rate of children and adults who are three (3) years and older in clinics and hospitals. The arm size is from 12 cm (4.7 inches) to 50 cm (19.7 inches). It can detect irregular heartbeats and display a symbol on its display and transmit the measurement by Bluetooth to other devices, such as PC, mobile phones, and gateways.

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.

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

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510(k) Summary

This 510(k) summary provides information to demonstrate substantial equivalence and is submitted in accordance with the requirement of 21 CFR 807.92.

1. Date Prepared

October 4, 2022

2. Submitter's Information

A&D Engineering, Inc.
Ms. Chanda Melville
4622 Runway Boulevard, Ann Arbor, MI 48108
Tel: 678-230-8565
Email: cmelville@andonline.com

3. Device Information

Proprietary Name:	A&D Medical UM-212BLE Blood Pressure Monitor
Regulation Number:	21 CFR 870.1130, 21 CFR 870.1120
Regulation Name:	Noninvasive Blood Pressure Measurement System
Regulatory Class:	Class II
Product Code:	DXN, DXQ

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

- A&D Medical UM-211 Digital Blood Pressure Monitor 510(k) number K173191
- A&D Medical UA-767PBT Digital Blood Pressure Monitors with 510(k) number K043217

5. Indications for Use

UM-212BLE blood pressure monitor is designed to measure systolic, diastolic pressure, and pulse rate of children and adults who are three (3) years and older in clinics and hospitals. The arm size is from 12 cm (4.7 inches) to 50 cm (19.7 inches). It can detect irregular heartbeats and display a symbol on its display and transmit the measurement by Bluetooth to other devices, such as PC, mobile phones, and gateways.

6. Intended Use

A&D Medical UM-212BLE Blood Pressure Monitor is designed for use in clinics and hospitals. It measures systolic, diastolic, and pulse rate. UM-212BLE uses the oscillometric and auscultatory methods to determine blood pressure.

7. Device Description – Technological and Operational Characteristics Comparison

UM-212BLE Blood Pressure Monitors have the same design as the predicate devices with an inflatable cuff which is wrapped around the patient's upper arm. The blood pressure measurement starts with the inflation process by an internal pump. The systolic and diastolic blood pressures are determined by oscillometric method during the deflation process. 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. UM-212BLE Blood Pressure Monitor will not inflate the cuff higher than 299 mmHg. The device will display an irregular heartbeat indicator if an irregular heartbeat was detected during the measurement process. At the end of the measurement, the systolic and diastolic pressure reading with pulse rate are shown on the LCD. The values can also be

transmitted by Bluetooth communication. The cuff is automatically deflated to 0 mmHg at the same time that the measurement is being displayed. If the monitor receives no further action from the user for 1 minute, it will automatically turn off.

UM-212BLE shares the same design and technologies with the two comparison models. Refer to the product comparison table below for the differences among these three models.

PRODUCT SPECIFICATION COMPARISON TABLE			
	Predicate Device		Modified Device
	UA-767PBT	UM-211	UM-212BLE
Measurement method	Oscillometric	Oscillometric and Auscultatory	Oscillometric and Auscultatory
Blood Pressure Measurement	Automatic (One-time)	Automatic (One-time) Auscultation	Automatic Multiple measurement (Average) Auscultation
AOBP (multiple measurement mode)	N/A	N/A	2 times, 3 times
First Measurement Wait Time	N/A	N/A	0 sec, 3 min, 5 min, 10 min
Measurement Interval	N/A	N/A	30 sec, 1 min, 2 min
BP Measurement Range	Systolic: 60 – 279 mmHg Diastolic: 40 – 200 mmHg Pulse: 40 – 200 beats per minute	Systolic: 60 – 279mmHg Diastolic: 40 – 200 mmHg Pulse: 40 – 200 beats per minute	Systolic: 60 – 279 mmHg Diastolic: 40 – 200 mmHg Pulse: 40 – 200 beats per minute
Pressure Measurement Range	0 – 299 mmHg	0 – 299 mmHg	0 – 299 mmHg
Measurement Accuracy	BP: ± 3 mmHg Pulse: ±5%	BP: ± 3mmHg Pulse: ± 5%	BP: ±3 mmHg Pulse: ±5%
Deflation Method	Mechanical exhaust valve	Constant speed electrical controlled exhaust valve	Constant speed electrical controlled exhaust valve
Pressure Sensor	Capacitance type	Semiconductor type	Semiconductor type
Bluetooth Communication	Bluetooth ver2.1	N/A	Bluetooth low energy ver 4.1
Cuff Size	Small Size: 16-24 cm Medium Size: 24-36cm Large Size: 36-45 cm	Small Size: 16-24 cm Adult Size: 22-32cm Large Size: 31-45 cm Extra Large Size: 41-50 cm	Extra Small Size: 12 – 17cm Small Size: 16-24 cm Adult Size: 22-32cm Large Size: 31-45 cm Extra Large Size: 41-50 cm
Memory Size	200	99	99

8. Modifications made from the predicate devices (UM-211 & UA-767PBT):

- Modify the internal layout of the circuit and components, and ISO/IEC 80369-5 compliant cuff hose connector.

- Include AOBP mode setting (multiple measurement mode)
- Update Bluetooth technology to Bluetooth low energy ver4.1
- Add extra small cuff size

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

A&D Medical conducted design verification and design validation activities based on comparisons of the UM-211 and UA-767PBT predicate devices. Based on the changes, we conducted the appropriated test methodology and pass/fail criteria. After the tests were conducted, the test records were added to the UM series design history file (DHF).

A&D Medical follows FDA recognized consensus standards and guidance documents in our medical device development and manufacturing processes. The following standards were used for the design verification and evaluation of UM-212BLE blood pressure monitor. These standards include the general quality system requirements, the special requirements for CDRH (870.1130), and 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 5-40)

- AAMI/ANSI/IEC 60601-1:2005
  Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (FDA Recognized Number 19-4)

- AAMI/ANSI/IEC 60601-1-2:2014
  Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances – Requirements And Tests (FDA Recognized Number 19-8)

- 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 3-152)

- AAMI/ANSI/IEC 62304:2006
  Medical Device Software - Software Life Cycle Processes (FDA Recognized Number 13-79)

- AAMI/ANSI/ISO 81060-2:2013
  Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type (FDA Recognized Number 3-130)

10. Substantial Equivalence Conclusion:

Test Summary based on FDA recognized standards:

- Safety & Performance IEC 60601-1:2005
- Safety & EMC Tests: IEC 60601-1-2: 2014
- Reliability Tests: ASMI/ANSI/IEC 80601-2-30:2009 & A1:2013
- Risk Assessment: ISO 14971:2012
- Software Assessment: IEC 62304 Software Life Cycle Process
- Clinical BP Measurement: ISO 81060-2:2013

The summary of the test results of ISO 81061-2 is listed below. UM-212BLE passed all blood pressure measurement accuracy requirements.

Standard Requirements		**Test Result**	**Result**
Criterion 1: Max Mean error of measurement & Standard deviation	Mean : ± 5.0 mmHg	Mean value: SYS = +3.05 mmHg DIA = +2.87 mmHg	Pass
	S. D. : 8.0 mmHg or less	Std deviation: SYS = 3.59 mmHg DIA = 3.48 mmHg	Pass
Criterion 2: Max Mean error of measurement & Standard deviation meet ISO 81060-2:2013 Table 1	SYS=6.20 mmHg, DIA=6.30 mmHg	Std deviation: SYS = 3.50 mmHg DIA = 3.11 mmHg	Pass
Standard Requirements		**Test Result (Test on Child)**	**Result**
Criterion 1: Max Mean error of measurement & Standard deviation	Mean : ± 5.0 mmHg	Mean value: SYS = +3.74 mmHg DIA = +2.88 mmHg	Pass
	S. D. : 8.0 mmHg or less	Std deviation: SYS = 1.15 mmHg DIA = 1.55 mmHg	Pass
Criterion 2: Max Permissible Standard Deviation per ISO 81060-2:2013 Table 1	SYS=5.77 mmHg, DIA=6.30 mmHg	Std deviation: SYS = 1.04 mmHg DIA = 1.37 mmHg	Pass

UM-212BLE met all applicable requirements of the FDA recognized consensus standards and guidance documents. None of the test demonstrated that the UM-212BLE bring new issues of safety and effectiveness.

As a conclusion, UM-212BLE 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.