March 21, 2019

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

Re: K173191
Trade/Device Name: A&D Medical UM-211 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: February 20, 2019
Received: February 22, 2019

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Shawn W. Forrest -S
2019.03.21 12:35:17 -04'00'

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)*
K173191

Device Name
A&D Medical UM-211 Digital Blood Pressure Monitor

Indications for Use *(Describe)*
UM-211 blood pressure monitor is designed to measure systolic, diastolic pressure, and pulse rate of adults who are twelve (12) years and older in the clinics and hospitals. The arm size is from 16 cm (6.3 inches) to 50 cm (19.7 inches). UM-211 can measure blood pressure in auscultatory (device class DXQ) and oscillometric (device class DXN) methods. It can detect irregular heartbeats and display a symbol on its display.

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 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

March 22, 2018

2. Submitter's Information

A&D Engineering, Inc.
Mr. Jerry Wang
1756 Automation Parkway, San Jose, CA 95131
Tel: 408-334-3326
Email: jwang@andonline.com

3. Device Information

Proprietary Name:	A&D Medical UM-211 Digital Blood Pressure Monitor
Regulation Number:	21 CFR 870.1130
Regulation Name:	Noninvasive Blood Pressure Measurement System
Regulatory Class:	Class II
Product Code:	DXQ & DNX

4. Information of the Predicate Devices

- A&D Medical UM-101 Digital Blood Pressure Monitor with 510(k) number K061456
- A&D Medical UA-1000 Series Digital Blood Pressure Monitors with 510(k) number K111686

5. Indications for Use

UM-211 blood pressure monitor is designed to measure systolic, diastolic pressure, and pulse rate of adults who are twelve (12) years and older in the clinics and hospitals. The arm size is from 16 cm (6.3 inches) to 50 cm (19.7 inches). UM-211 can measure blood pressure in auscultatory (device class DXQ) and oscillometric (device class DXN) methods. It can detect irregular heartbeats and display a symbol on its display.

6. Intended Use

A&D Medical UM-211 Digital Blood Pressure Monitor is designed at clinics and hospitals by medical professionals to measure blood pressure of patients defined in the Indications for Use above.

7. Device Description – Technological and Operational Characteristics Comparison

UM-211 Digital 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. Furthermore, there is a maximum pressure safety setting at 299 mmHg. UM-211 Digital Blood Pressure Monitor will not inflate the cuff higher than 299 mmHg. UM-211 will turn on an irregular heartbeat indicator if an irregular heartbeat was detected during the measurement process. For the oscillometric method, systolic and diastolic are determined by the internal algorithm. For the auscultatory method,

systolic and diastolic are determined by the medical professionals. The results are shown on the LCD. The cuff is also deflated automatically to 0 mmHg at the same time. This auscultatory method is identical to the predicate device, UM-101 digital blood pressure monitor. The oscillometric method is identical to the predicate device with the capability to perform averaging function of multiple measurements (AOBP mode).

UM-211 also detects the patient daily activities and environmental conditions of ambient temperature and barometric pressure. These are non-medical features which will be only available for the medical professionals to review. These information are not displayed to the patient on the TM-2441 display. The BP waveform is another non-medical feature which can be used by the medical professional and A&D engineers to verify the accuracy of the blood pressure measurement. Basically, we can reconstruct the systolic, diastolic, and pulse rate from the BP waveform. There is no other medical diagnose from the information of the BP waveform.

If the monitor receives no further action from the user for 1 minute, it will automatically turn off by itself and waiting for the next measurement timing. UM-211 has a memory capacity of 99 for the previous measurements.

8. Summary of Substantial Equivalence

Modifications made from the predicate devices (UM-101 & UA-1000 series):

- Modify the external industrial design for a different appearance.
- Modify the internal layout of the circuit and components.
- Increase the number of supported cuff size from 3 sizes to 4 sizes.
- Power source – Adding rechargeable battery
- Combine the oscillometric and auscultatory methods

Discussion of standards used in the design verification and design validation

A&D Medical conducted design verification and design validation activities based on the comparison of the UM-211 with the 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 collected in 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 to for the design verification and valuation of UM series digital blood pressure monitors. 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)

- 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/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)

9. Substantial Equivalence Conclusion:

Test Summary based on FDA recognized standards:

- Safety & 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 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 series passed all blood pressure measurement accuracy requirements.

Standard Requirements		Test Result	Result
Criterion 1: Mean value & Standard deviation	Mean : ± 5mmHg or less S. D. : 8mmHg or less	Mean value: SYS = 3.05 mmHg DIA = 2.87 mmHg Std deviation: SYS = 3.59 mmHg DIA = 3.48 mmHg	Passed
Criterion 2: Standard deviation	SYS=6.20, DIA=6.30 or less	Std deviation: SYS = 3.50 mmHg DIA = 3.11 mmHg	Passed

UM-211 met all applicable requirements of the FDA recognized consensus standards and guidance documents. None of the test demonstrated that UM-211 brings new issues of safety and effectiveness.

As a conclusion, UM-211 digital blood pressure monitor as described in its labeling and comparison analysis has not changed because 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.