April 24, 2019

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

Re: K173065
Trade/Device Name: A&D Medical TM-2440 & TM-2441 Digital Blood Pressure Monitors
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: March 22, 2019
Received: March 25, 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,

Stephen C. Browning -S5

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)*
K173065

Device Name
A&D Medical TM-2440 & TM-2441 Digital Blood Pressure Monitors

Indications for Use *(Describe)*
TM-2440 and TM-2441 blood pressure monitors are designed to monitor systolic and diastolic pressure, and pulse rate of adults who are twelve (12) years and older by using the oscillometric method.

TM-2441 has four environmental functions to measure activity monitoring (3-axis accelerometer) , ambient temperature monitoring, barometric pressure monitoring, and waveform capability. These functions are not observed by patients form the device display and can only be used by the medical professionals.

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

August 13, 2018

2. Submitter's Information

A&D Engineering, Inc.
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3. Device Information

Proprietary Name:	A&D Medical TM-2440 & TM-2441 Digital Blood Pressure Monitors
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 TM-2430 & TM-2431 Digital Blood Pressure Monitors with 510(k) number K992808

5. Indications for Use

TM-2440 and TM-2441 blood pressure monitors are designed to measure systolic and diastolic pressure, and pulse rate of adults who are twelve (12) years and older by using the oscillometric method. The arm size is from 15 cm (5.9 inches) to 50 cm (19.6 inches).

TM-2441 has four environmental functions to measure activity monitoring (3-axis accelerometer), ambient temperature monitoring, barometric pressure monitoring, and waveform capability. These functions are not observed by patients form the device display and can only be used by the medical professionals.

6. Intended Use

A&D Medical TM-2440 & TM-2441 Digital Blood Pressure Monitors is designed for adult at home or clinic use. It measures systolic, diastolic, and pulse rate. TM-2440 & TM-2441 uses the oscillometric method to determine blood pressure. TM-2441 has a self-measurement button to enable the patient to take a measurement whenever it is needed. Both devices have an USB port

to be connected. TM-2441 also has *Bluetooth*® low energy wireless (BLE) communication capability with Smart devices. TM-2440 & TM-2441 fits arm size from 15 cm to 50 cm.

7. Device Description – Technological and Operational Characteristics Comparison

TM-2440 & TM-2441 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. There is a maximum pressure safety setting at 299 mmHg. TM-2440 & TM-2441 Digital Blood Pressure Monitors will not inflate the cuff higher than 299 mmHg. TM-2440 & TM-2441 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 and waiting for the next measurement timing.

8. Summary of Substantial Equivalence

Modifications made from the predicate devices:

- Modify the internal layout of the circuit and components.
- Increase the number of supported cuff size from 3 sizes to 4 sizes.
- Change LCD display to OLED display.
- Change power source from 3 pcs of AA batteries to 2 pcs of AA batteries.
- Change communication method from RS-232C to USB and BLE.
- Increase the memory size from 300 to 600.
- Add non-medical function - activity data by 3-axis accelometer, ambient temperature, barometric pressure, and waveform capability.

Product Specification Comparison Table:

Model	**Predicate Devices**	**Modified Device**	
	TM-2430 & TM-2431	**TM-2440**	**TM-2441**
Measurement Method	Oscillometric Method	No Change	No Change
BP Measurement Range	Systolic: 60 – 280mmHg Diastolic: 40 – 160 mmHg Pulse: 30 – 200 beats per minute	Systolic: 60 – 280mmHg Diastolic: 30 – 160 mmHg Pulse: 30 – 200 beats per minute	Systolic: 60 – 280mmHg Diastolic: 30 – 160 mmHg Pulse: 30 – 200 beats per minute
Pressure Measurement Range	0 – 299 mmHg	No Change	No Change

Measurement Accuracy	BP: +/- 3mmHg Pulse: +/- 5%(pulse)	No Change	No Change
Minimum Display Resolution	1 mmHg	No Change	No Change
Pressure sensor	Semiconducting type sensor	No Change	No Change
Pressurization Source	Automatic micro pump	No Change	No Change
Cuff Deflation Method	Rapid exhaust valve	No Change	No Change
Cuff Attachment Method	By plastic hose connected to monitor	No Change	No Change
Power Source	3xAlkaline battery or 3xNickel-hydrogen battery	2xAlkaline battery or 2xNickel-hydrogen battery	2xAlkaline battery or 2xNickel-hydrogen battery
Battery Life	At least 200 measurements for a set of alkaline battery	No Change	No Change
Type of protecting against electric shock	Internally powered equipment type BF	No Change	No Change
Self / Event Measurement Mode	Enabled	Disabled	Enabled
Operating Environment	50°F(10°C) to 104°F(40°C) at less than 85%RH	No Change	No Change
Storage Environment	-4°F(-20°C) to 140°F(60°C) at less than 85%RH	No Change	No Change
Data Memory Size	Last 300 measurements of systolic, diastolic, and pulse rate	Last 600 measurements of systolic, diastolic, and pulse rate	Last 600 measurements of systolic, diastolic, and pulse rate
Dimensions	72 x 100 x 27(mm)	66 x 95 x 24.5(mm)	66 x 95 x 24.5(mm)
Weight	Approx.146(g)	Approx.120(g)	Approx.135(g)
Cuff Size	Small Size: 15-22 cm Adult Size: 20-31cm Large Size: 28-36 cm	Small Size: 15-22 cm Adult Size: 20-31cm Large Size: 28-36 cm Extra Large Size: 36-50 cm	Small Size: 15-22 cm Adult Size: 20-31cm Large Size: 28-36 cm Extra Large Size: 36-50 cm
Arm Size	15 to 36 cm	15 to 50 cm	15 to 50 cm

Display Type and Size	LCD:29.5 x 8(mm)	OLED:20 x 8.5(mm)	OLED:20 x 8.5(mm) LCD:39 x 45(mm)
Waveform Recording	Disabled	Enabled	Enabled
Non-medical Data Collection	Disabled	Disabled	Enabled (activity, ambient temperature, biometric pressure, waveform capability)
Connectivity Interface	USB	USB	USB & BLE
Field service	Not allowed	No Change	No Change
Automatic Zero at "START"	Yes	No Change	No Change
Manual Zero Adjustment	Not allowed	No Change	No Change
Calibration	Not allowed in the field	No Change	No Change
Sterilization	Not needed	No Change	No Change

9. **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 TM-2440 and TM-2441 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 TM-2440 and TM-2441 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 TM-2440 and TM-2441 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)

10. Substantial Equivalence Conclusion:

- 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
- Bluetooth Tests: FCC Part 15 Subpart C : 2014
- Clinical BP Measurement: ISO 81060-2:2013

The summary of the test results of ISO 81061-2 is listed below. TM-2440 and TM-2441 passed all blood pressure measurement accuracy requirements.

Standard Requirements		**Test Result**	**Result**
Criterion 1: Mean value & Standard deviation	± 5mmHg or less 8mmHg or less	Mean value: SYS = -0.80 mmHg DIA = -0.94 mmHg Std deviation: SYS = 6.46 mmHg DIA = 6.45 mmHg	Passed
Criterion 2: Standard deviation	SYS=6.89, DIA=6.88 or less	Std deviation: SYS = 5.13 mmHg DIA = 5.86 mmHg	Passed

TM-2440 & TM-2441 digital blood pressure monitors have the following similarities to the predicate devices, TM-2430 & TM-2431, which previously received 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 production facility
- Same Indications For Use

As a conclusion, TM-2440 & TM-2441 digital blood pressure monitors 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 device.