



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

April 13, 2016

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

Re: K151953

Trade/Device Name: A&D Medical TM-2657 Family of 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: February 29, 2016
Received: March 3, 2016

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

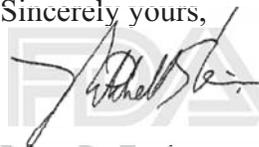
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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 yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, large watermark of the FDA logo.

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K151953

Device Name
A&D Medical TM-2657 Family Digital Pressure Monitors

Indications for Use (Describe)

TM-2657, TM-2657P, TM-2657PBT, and TM-2657PRS are designed to measure blood pressure (systolic and diastolic) and pulse rate in adult patients with arm circumference range between 7.1 inches (18.0 cm) and 13.8 inches (35.0 cm).

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)

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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

February 29, 2016

2. Submitter's Information

A&D Engineering, Inc.

Mr. Jerry Wang

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Tel: 408-518-5113

Fax: 408-635-2313

Email: jwang@andonline.com

3. Device Information

Proprietary Name: A&D Medical TM-2657 Family of Digital Blood Pressure Monitors

Common/Usual Name: Blood Pressure Monitor

Classification name: Non-invasive blood pressure measurement System
21 CFR 870.1130, Class II, DXN.

4. Predicate Devices

- A&D Model UA-767PBT Digital Blood Pressure Monitor with 510(k) number K043217
- A&D Model TM-2655 Family (TM-2655, TM-2655P and TM-2655PV) of Digital Blood Pressure Monitors with 510(k) number K010828

Both predicate devices are designed and manufactured by the same company and facilities as the modified devices, TM-2657 Family of Digital Blood pressure Monitors.

5. Indications for Use

TM-2657, TM-2657P, TM-2657PBT, and TM-2657PRS are designed to measure blood pressure (systolic and diastolic) and pulse rate in adult patients with arm circumference range between 7.1 inches (18.0 cm) to 13.8 inches (35.0 cm).

6. Device Description – Technological and Operational Characteristics Comparison

TM-2657 Family of digital blood pressure monitors have the same design as the predicated devices with an inflatable cuff which is wrapped around the patient's upper arm. After the user pushes the "START" button, 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 urgently. There is a maximum pressure safety setting at 299 mmHg. TM-2657 Family of digital blood pressure monitors will not inflate the cuff higher than 299 mmHg. TM-2657 Family of digital blood pressure monitors 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 LCD and printed by the internal printer or transmitted via Bluetooth wireless module if it is installed. The cuff is also deflated automatically to 0 mmHg at the same time. The detail of summary of substantial equivalence is listed below.

7. Summary of Substantial Equivalence

Modifications made from the predicate devices:

- Change the plastic molds so the TM-2657 Family of Digital Blood Pressure Monitors have a new appearance.
- Enable the same Bluetooth wireless communication capability of UA-767PBT to the new TM-2657 Family of digital blood pressure monitors.
- Reduce the arm size from 5.1 inches (13 cm) – 17.7 inches (45 cm) to 7.1 inches (18 cm) – 15.7 inches (40 cm).
- Remove the voice/talking capability.

Product Specification Comparison

Parameter	Predicate Devices (TM-2655 Family & UA-767PBT)	Modified Devices (TM-2657 Family)
Power source	Transformer power supply 120V AC 60Hz	Switching power supply 100-240V AC 50/60Hz
Protection against electrical shock	Class I, Type B	No change – the same
Measurement Method	Oscillometric Method	No change – the same
Pressure display range	0-300mmHg	0-299 mmHg
Minimum display resolution	1 mmHg	No change – the same
Pressure Sensor design	Capacitance type pressure transducer	No change – the same
NIBP Clinical test	AASI/AAMI SP-10 :1992	BS EN1060-4:2004, BHS:1993
NIBP Measurement range	Blood Pressure: 10-280mmHg Pulse: 30-200bpm	SYS: 40-270 mmHg DIA: 20-200 mmHg Pulse: 30-240 bpm
Accuracy	BP : +/- 3%, Pulse : +/- 5 %	No change – the same
Pressurization Source	Automatic internal air pump	No change – the same
Cuff Design	Winding mechanism operated by geared motor	No change – the same
Air Pressure Control Method	Rubber valve with ceramic valve	Rubber valve with electrical control valve
Exhaust Method	Automatic rapid exhaust by electromagnetic valve	No change – the same
Display Type	3-digit display by LED	No change – the same
Cuff Attachment Method	By plastic hose connected to monitor	No change – the same
IHB (Irregular Heartbeats Detection)	More than +/-25% to the mean interval of all pulse intervals	No change – the same
Operating	50 ⁰ F (10 ⁰ C) to 104 ⁰ F (40 ⁰ C) with	50 ⁰ F (10 ⁰ C) to 104 ⁰ F (40 ⁰ C)

Environment	85% RH or less , no condensing	with 15 %RH to 85% RH, no condensing
Storage Environment	14 ⁰ F (-20 ⁰ C) to 140 ⁰ F (60 ⁰ C) with 95% RH or less, no condensing	14 ⁰ F (-20 ⁰ C) to 140 ⁰ F (60 ⁰ C) with 10 -95% RH, no condensing
Arm Size	5.1 inches (13 cm) to 17.7 inches (45 cm)	7.1 inches (18 cm) to 15.7 inches (40 cm)
Printer function	Thermometer Printer	No change – the same
External dimensions	245 (W) x 322 (H) x 390 (D) mm	241 (W) x 330 (H) x 390 (D) mm
Weight	Approx. 9 kg	Approx. 5.5 kg
Connectivity	Wired – RS232C standard (TM-2655 Family) Wireless – Bluetooth 2.1 Standard (UA-767PBT)	No change – the same
Voice/Talking Capability	TM-2655V enabled	Disabled

Key Features Comparison

Parameter	Predicate Devices (TM-2655 Family & UA-767PBT)	Modified Devices (TM-2657 Family)
Field service	Not allowed	No Change – the same
Automatic zero at “START”	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

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

We conducted design verification and design validation activities based on the comparison of the TM-2657 Family of digital blood pressure monitors 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 design history file (DHF).

A&D Medical follows FDA regulation and international standards in our medical device development and manufacturing processes. The following standards were used to demonstrate compliance to FDA recognized consensus standards for the TM-2657 Family of digital blood pressure monitors devices.

- ANSI/AAMI/IEC 80601-2-30:2009 Medical electrical equipment — Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers.
- AAMI/ANSI 60601-1:2006 Medical electrical equipment. General requirements for basic safety and essential performance
- AAMI/ANSI/IEC 60601-1-2:2007 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests
- AAMI/ANSI/ISO 14971:2012 Medical devices. Application of risk management to medical devices

TM-2657 Family of digital blood pressure monitors met all applicable requirements of the standards. None of the test demonstrated that the TM-2657 Family of digital blood pressure monitors bring new issues of safety and effectiveness.

9. Evaluation Performance & Substantial Equivalence Conclusion:

TM-2657 family digital blood pressure monitors pass the clinical and non-clinical evaluation based on the followed table.

Non-clinical Test Summary:

- Safety Tests: IEC 60601-1:2006
- EMC Tests: AAMI/ANSI/IEC 60601-1-2:2007
- Reliability Tests: IEC80601-2-30:2009+CI:2010
- Risk Assessment: ISO 14971:2012
- Bluetooth Tests: FCC 47 CFR Part 15.247 & EN 300 328 V1.8.1 (2012-06)

Clinical Test Summary based on BS EN 1060-4:2004 / ISO 141155-1 & -2:2003:

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 40% or more	43	50.6%	Pass
	Female 40% or more	42	49.4%	Pass
Age	Older than 50 : 50-75%	44	51.8%	Pass
Circumference of Arm	18 – 35 cm : 50-75%	49	57.6%	Pass
BP Range	SYS<110mmHg at least 10%	18	21.2%	Pass
	SYS>160mmHg at least 10%	24	28.2%	Pass
	DIA<70mmHg at least 10%	17	20.0%	Pass
	DIA>100mmHg at least 10%	29	34.1%	Pass
Measurement Result	Average : +/-5mmHg or less	SYS	-0.99mmHg	Pass
		DIA	-1.09mmHg	Pass
	S.D. : 8mmHg or less	SYS	7.62mmHg	Pass
		DIA	5.87mmHg	Pass

TM-2657 Family of digital blood pressure monitors Digital blood pressure monitors have the following similarities to the predicate devices, TM-2655 Family 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 deflation method – standard exhaust valve
- Same materials, no new materials used
- Same manufacturing processes at the same facility
- Reduced Indication of Use in arm circumference range.

Predicated Devices (TM-2655 Family)	Modified Devices (TM-2657 Family)
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The A&D Medical LifeSource TM-2655, TM-2655P & TM-2655VP are designed to measure blood pressure (diastolic and systolic) and pulse rate in adult patients with arm circumference range between 5.1 inches (13 cm) to 17.7 (45 cm)	TM-2657, TM-2657P & TM-2657PRS & TM-2657PBT are designed to measure blood pressure (diastolic and systolic) and pulse rate in adult patients with arm circumference range between 7.1 inches (18 cm) to 15.7 (40 cm)
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As a conclusion, TM-2657 Family of digital blood pressure monitors as described in its labeling and comparison analysis, have not changed as a result of the modifications. The fundamental scientific technology of the modified devices 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.