K082734
P1/3

Attachment (D) 510(k) Summary

1. DATE PREPARED

October 17, 2008

NOV 13 2008

2. CONTACT INFORMATION

A&D Engineering, Inc.
Mr. Jerry Wang
1756 Automation Parkway,
Tel: 408-518-5113
Fax: 408-635-2313
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3. DEVICE NAME

Proprietary Name:	A&D Medical UA-851THW Digital Blood Pressure Monitor
Common/Usual Name:	Blood Pressure Monitor
Classification name:	Non-invasive blood pressure measurement System 21 CFR 870-1130, Class II, 74DXN.

4. DEVICE DESCRIPTION AND INTENDED USE

The A&D Medical UA-851THW digital blood pressure monitor is intended for used by adults with 12 years older to measure the systolic and diastolic blood pressure and pulse rate.

5. PREDICATE DEVICE

A&D LifeSource model UA-767PBT digital blood pressure monitor with FDA 510(k) K043217
A&D LifeSource model UA-789 digital blood pressure monitor with FDA 510(k) K062027.
Both devices are designed and manufactured by the same company and facility as the UA-851THW digital blood pressure monitor.

6. TECHNOLOGICAL and OPERATIONAL CHARACTERISTICS

UA-851THW uses an inflatable cuff which is wrapped around the patient's upper arm. The cuff is inflated automatically by an internal pump in the device. The systolic and diastolic blood pressures are determined by oscillometric method. The deflation rate is controlled by the internal electronic-controlled exhaust valve. There is a quick exhaust mechanism so that the pressure of the cuff can be completely released. There is a maximum pressure safety setting at 300mmHg. The cuff will inflate higher than 300mmHg. The arm distribution range is from 5.1" to 17.7" (13 cm to 45 cm). At the end of the measurement, the result can be uploaded to a PC with ActiLink USB transceiver and viewed by the Wellness Connected software.

7. SUMMARY OF SUBSTANTIAL EQUIVALENCE

Product Specification Comparison

Parameter	**Predicate Devices (UA-789 & UA-767PBT)**	**UA-851THW**
Measurement Method	Oscillometric Method	No change – the same
Measurement Range	BP : 20 to 280 mmHg Pulse : 30 to 200 pulse/min	No change – the same
Accuracy	BP : +/- 3mmHg or +/- 2% of measured value, whichever is greater Pulse : +/- 5 % (pulse)	No change – the same
Pressurization Source	Automatic internal pump	No change – the same
Cuff Deflation	Automatic constant speed mechanical exhaust valve	No change – the same
Data Memory Size with Time & Date	40 memories for UA-767PBT 60 memories for UA-789	51 memories
Irregular Heartbeats Detection	More than +/-25% to the mean interval of all pulse intervals	No change – the same
Power Source	6V DC, 4x1.5V AA batteries or AC adapter as an option	No change – the same
Battery Life	4 months with daily measurement	No change – the same
Operating Environment	50^0F (10^0C) to 104^0F (40^0C) at less than 85% RH	No change – the same
Storage Environment	14^0F (-20^0C) to 140^0F (60^0C) at less than 85% RH	No change – the same
Dimensions	80(H) x 110(W) x 120(L) mm	160(H) x 150(W) x 125(L) mm

Cuff Attachment Method	By plastic hose connected to monitor	No change – the same
Arm Size	UA-767PBT – 5.1" to 17.7" (13 cm to 45cm) UA-789 - 9.4" to 23.6" (24 cm to 60 cm)	No change – the same as UA-767PBT
Weight	UA-767PBT - 920 g (2.03 lb) without batteries UA-789 - 940 g (2.07 lb) without batteries	930 g (2.05 lb) without batteries
Display Type	Liquid crystal display	No change – the same

Major changes from the predicate devices:

- Replace the radio in the UA-767PBT with a new one into UA-851THW
- Change the plastic molds from UA-789 to UA-851THW

These changes do not affect the devices' intended use or alter the device's fundamental scientific technology. There is no significant difference that affects the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2008

A & D Engineering, Inc.
c/o Mr. Jerry Wang
Director of Engineering
1756 Automation Parkway
San Jose, CA 95131

Re: K082734
Trade/Device Name: A&D Medical LifeSource UA-851THW Digital Blood Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: October 17, 2008
Received: October 22, 2008

Dear Mr. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082734

Attachment B

Indications for Use

510(k) Number (if known): K082734

Device Name: A&D Medical LifeSource UA-851THW Digital Blood Pressure Monitor

Indications For Use:

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

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vollmer
(Division Sign-Off)
Division of Cardiovascular Devices

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