K062027
p1/2

Attachment (D) 510(k) Summary

1. DATE PREPARED

July 14, 2006 (original).
September 1, 2006 (revised).

JAN 19 2007

2. SPONSOR INFORMATION

A&D Engineering, Inc.
Mr. Jerry Wang
1555 McCandless Drive, Milpitas, CA 95035
Tel: 408-518-5113
Fax: 408-635-2313
Email: jwang@andmedical.com

3. DEVICE NAME

Proprietary Name:	A&D Medical UA-789 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-789 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-787 digital blood pressure monitor with FDA 510(k) K012472.

6. TECHNOLOGICAL CHARACTERISTICS

UA-789 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. The arm distribution range is from 9.4" to 23.6" (24 cm to 60 cm).

The accuracy and effectiveness of the extra large cuffs used in UA-789 have been validated through the ANSI/AAMI SP-10 standard.

7. DEVICE TESTING

A&D Medical UA-789 digital blood pressure monitor meets the following standards:

- ANSI/AAMI SP-10 standard
- European Directive 93/42 EEC for Medical Products
- EN60601 General Safety Provisions
- EN60601-2-30 Particular Requirements for the Safety of BP Monitor
- EN60601-1-2 and EN55011 Electromagnetic Compatibility

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

A&D Engineering, Inc.
c/o Mr. Jerry Wang
Director of Engineering and QA
1555 McCandless Dr.
Milpitas, CA 95035

JAN 19 2007

Re: K062027
Trade Name: A&D Medical LifeSource UA-789 Digital Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive blood pressure measurement system
Regulatory Class: Class II (two)
Product Code: DXN
Dated: January 3, 2007
Received: January 4, 2007

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

K062027

Attachment B

Indications for Use

510(k) Number (if known):_____

Device Name: A&D Medical LifeSource UA-789 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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062027