DEC - 3 2004

K042967
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Attachment (D) 510(k) Summary

1. DATE PREPARED

Oct. 20, 2004

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 LifeSource UB-511 & UB-512 Digital Blood Pressure Monitors
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 LifeSource UB-511 & UB-512 digital blood pressure monitors are intended for use by adults for measuring the systolic and diastolic blood pressure and pulse rate.

5. PREDICATE DEVCIE

It is substantially equivalent to the following three devices:
A&D UB-401, FDA 510(k) K002115. Issued on July 25, 2000

A&D UA-328, FDA 510(k) K040229. Issued on June 30, 2004

6. TECHNOLOGICAL CHARACTERISTECS

UB-511 & UB-512 use an inflated cuff which is wrapped around the wrist. The cuff is inflated automatically by the air pump. The systolic and diastolic blood pressures are determined by oscillometric method while the cuff is inflated. The pressure of the cuff

is completely released automatically at the end of the measurement. At the same time, the measurements are displayed on the LCD display for one minute. The blood pressure results are compared with WHO (World Health Organization) BP classifications, which are Sever Hypertension, Moderate Hypertension, Mild Hypertension, High Normal, Normal, and Optimal. The corresponding LCD segment will be turned on along with the systolic, diastolic, and pulse rate information. UB-511 & UB-512 measure blood pressure and pulse rate even when an irregular heartbeat occurs. After one minute without operation, UB-511 & UB-512 turns off automatically.

7. DEVICE TESTING

A&D LifeSource UB-511 & UB-512 digital blood pressure monitors meet NIST/AAMI SP-10 standard and FDA guidance "Non-invasive Blood Pressure (NIBP) Monitor Guidance". Please refer to the table below for the list of AAMI SP-10 tests. UB-511 & UB-512 are not clinically tested. It uses the identical software codes and pressure detection related hardware as the predicate devices to determine systolic, diastolic, and pulse rate.

SP-10 Section #	Section Title	Test Results & Comments
4.1.1	General	Conformed
4.1.2.1	Device labeling	Conformed
4.1.2.2	Outer container	Conformed
4.1.3	Information manual	Conformed
4.1.4.1	Component replacement	Conformed
4.1.4.2	Power system labeling	Conformed
4.1.4.3	Labeling for battery-powered devices	Conformed
4.2.1	Storage conditions	Conformed
4.2.2	Operating conditions	Conformed
4.2.3	Vibration and shock	Conformed
4.2.4.1	Voltage range	Conformed
4.2.4.2	Life	Conformed
4.3.1.1	Maximum cuff pressure	Conformed
4.3.1.2	Cuff deflation	Conformed
4.3.2	Electrical safety	Conformed
4.3.3	Conductive components	Conformed
4.4.1	Pressure indicator accuracy	Conformed
4.4.2	Overall system efficacy	Conformed
4.4.2.1	Auscultatory method as the reference standard	Conformed
4.4.2.2	Intra-aeterial method as the reference standard	Not applicable
4.4.3	Battery-powered devices	Conformed
4.5	Requirements for devices with manual inflation systems	Conformed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 3 2004

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

Re: K042967
Trade Name: A&D Medical LifeSource UB-511 & UB-512 Digital Blood Pressure Monitors
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: November 29, 2004
Received: November 30, 2004

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 (301) 594-4646. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

K042967

Attachment (B) Indications for Use Statement

510(k) Number (if known): _____

Device Name: A&D Medical LifeSource UB-511 & UB-512 Digital Blood Pressure Monitors

Indications for Use:

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

Prescription Use _____ or Over-The-Counter Use ____X____

(Optional Format 1-2-96)

(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 K042967