510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K061279

AUG 1 8 2006

1. Submitter's Identification:

Little Doctor (Shanghai) Electronic Manufacture Co., Ltd
Floor 3rd,1st Bldg ,No 4514 Caoan Road
Shanghai China

Tel: 0086-021-63056696

Date Summary Prepared: May 1, 2006

Contact: Mr. David Zhang

2. Name of the Device:

LD-578 Fully Automatic Digital Blood Pressure Monitor

3. Common or Usual Name:

Non-Invasive Blood Pressure Monitor System

4. Predicate Device Information:

The LD-578 Fully Automatic Digital Blood Pressure Monitor, is substantially equivalent to the AMPLIFE Upper Arm Blood Pressure Monitor, Model M100, AMPLIFE Corporation.

5. Device Description:

The LD-578 Fully Automatic Digital Blood Pressure Monitor, Model LD-578 is designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the Upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic semiconductor sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well-known technique in the market called the "oscillometric method".

6. **Intended Use:**

The LD-578 Fully Automatic Digital Blood Pressure Monitor is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.

7. **Comparison to the Predicate Device:**

The LD-578 Fully Automatic Digital Blood Pressure and predicate device (AMPLIFE Upper Arm Blood Pressure Monitor, Model M100, K043440) are identical in functionality and performance with the difference being the external shape of the device, dimensional specification and clock function. These differences have no impact on safety or performance of the device. The blood pressure measurement algorithm and its functional technology are identical.

Both the subject and predicate devices use the well known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate.

8. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing information demonstrating safety and effectiveness of the LD-578 Fully Automatic Digital Blood Pressure Monitor in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance Requirements.

The following testing was conducted:

a. General Functions Test
b. Reliability Test-Operation Conditions
c. Reliability Test-Drop Testing
d. Reliability Test-Storage
e. Reliability Test-Vibrating Testing
f. EMC Testing
g. IEC 60601-1 Safety Testing
h. FDA required Unit Intravariability Testing

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that the LD-578 Fully Automatic Digital Blood Pressure Monitor tested met all relevant requirements of the aforementioned tests.

9. **Discussion of Clinical Tests Performed:**

We have performed clinical testing on the LD-578 Fully Automatic Digital Blood Pressure Monitor according to "Clinical Data and Analysis ANSI/AAMI-SP-10 Standard, Section 4.4.2". All testing results met required parameters.

10. **Conclusions:**

We have demonstrated that the LD-578 Fully Automatic Digital Blood Pressure Monitor is as safe and effective as the predicate device based on electrical, mechanical and environmental testing results, and SP-10 standard requirements. FDA guidance document requirements were also met. Therefore, our subject device is as safe and effective as our predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 2006

Little Doctor (Shanghai) Electronic Manufacture Co., Ltd.
c/o Susan Goldstein-Falk
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K061279
Trade Name: LD-578 Fully Automatic Digital Blood Pressure Monitor
Regulation Number: 21 CFR §870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: July 31, 2006
Received: August 1, 2006

Dear Ms. Goldstein-Falk:

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,

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

Enclosure

Exhibit B

Indications for Use

510(k) Number (if known): K061279

Device Name: LD-578 Fully Automatic Digital Blood Pressure Monitor

Indications For Use:

The Shanghai Little Doctor LD-578 Fully Automatic Digital Blood Pressure Monitor, is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.

Prescription Use _____ **(Per 21 CFR 801 Subpart D)**	**OR**	**Over-The Counter Use** X **(21 CFR 807 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 K061279