K093359
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Attachment 2

510k summary

NOV 27 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Section 807.92. The assigned 510(k) number is:

A. General Information on submitter

1. *Submitter's Name:*	SHANGHAI LITTLE DOCTOR ELECTRONIC CO., LTD.
2. *Address:*	NO. 8, TONGXING ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT DISTRICT, NANTONG CITY, JIANGSU PROVINCE, 226007, CHINA
3. *Telephone:*	0086-513-8598 6718
4. *Contact Person:*	Mr. Janusun Wang
5. *Date Prepared:*	10/20/2009
6. *Registration Number:*	3005907323
7. *Owner Number of Registration:*	9086965

B. General information of modified devices

1. *Name:*	Digital BP monitor
2. *Trade Name:*	Digital blood pressure monitor, model LD 1103 and LD 1133
3. *Common Name:*	Electronic Sphygmomanometer
4. *Classification Name:*	System, measurement, blood pressure, non-invasive
5. *Product Code :*	DXN

C-2

6. *Class:* II
7. *Regulation Number:* 870.1130

C. Identification of FDA Cleared Devices(predicate)

1. *Name:* Digital blood pressure monitor, model LD 578
2. *K Number:* K061279
3. *Date Cleared:* August 18, 2006

D. Description of the Device

The Digital Blood Pressure Monitors, Model LD1103 and LD 1133, are designed to measure the systolic and diastolic blood pressure and pulse rate of an individual adult by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The 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 to calculate pulse rate, which is a well-known technique in the market called the "oscillometric method". The device can analyze the signals promptly and display the results.

E. Intended Use Statement

LD1103 and LD 1133 Digital Blood Pressure Monitor are intended for use by medical professionals in medical care facilities or by patients for self monitoring at home to monitor and display diastolic, systolic blood pressure and pulse rate of adult, with the cuff around the upper arm, which is same as predicate device.

F. Comparisons to the predicate

The modified devices have the same intended use and identical fundamental scientific principle called oscillometric BP measurement method. They are identical in safety and effectiveness of the intended use to the 510(k) cleared device model LD578. The modifications to our original 510(k) cleared device include dimensional specifications and adding new auxiliary features of WHO and date and time indication.

The modifications that were made are:

1. Appearance
2. WHO blood pressure classification indication
3. Increase the number of memory recalls
4. Date and time display
5. Inflation and exhaust components

6. Packaging and wording in instruction manual

Please find the following tabulated comparisons supporting that the modified devices are substantially equivalent to the predicate device with FDA 510K# K061279

Technological Characteristics Comparisons table

Intended use	identical
Fundamental scientific principle	Identical
Target population	Identical
Use at home or in hospital	Identical
Safety and effectiveness	Identical
Over the counter	Identical
Performance specifications	Identical
Stirility	Not applicable
Biocompatibility	Identical
Mechanical safety	Identical
Electrical safety	Identical
Standards met	Identical
Energy used or delivered	Identical
Environmental specifications	Identical
Ergonomics of the patient-user interface	Identical
Software	Similar
Packaging or labeling	Similar
Dimensional specification	Similar

G. Discussion of Similarities and Differences

The modified devices are identical to the predicate in functionality and performance ,with the only differences being the additional features, such as WHO indication, date and time display and an increased recall capacity of measurement results. The modifications to our original 510(k) cleared device include the dimensional specifications, inflation and exhaust components, packaging and labeling and subprogram of software for WHO indication and date and time display. The blood pressure measurement algorithm and its software codes of the modified devices remain unchanged. The fundamental scientific technology of the modified device remains the same as that of the 5l0(k) cleared device. These differences have no impact on safety or effectiveness of the device in use for blood pressure measurement.

H. Performance testing

The subjects have been tested and found otherwise to comply with the following standards:

* IEC/EN 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

*IEC/EN/ANSI 60601-1-2, Medical Electrical Equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and Test

* ISO 10993-1, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing

*ANSI/AAMI SP10-2002, Manual, Electronic or Automated Sphygmomanometers

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 - Vibration Testing
f. EMC Testing
g. IEC 60601-1 Safety Testing

None of the testing demonstrated any design characteristics that violated the requirement of the Reviewer Guidance or resulted in any safety hazards

I. Conclusions:

The LD1103 and LD 1133 Digital Blood Pressure Monitor are as safe and effective as the predicate device in intended use for blood pressure measurement, based on electrical, mechanical and environmental testing results, and SP-10 standard requirements. Therefore, these two modified devices are substantially equivalent to the predicate device in use for BP measurement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Shanghai Little Doctor Co. Limited
C/O Janusun Wang, Regulatory Affairs Representative
Shanghai Little Doctor Co. Limited
No. 8, Tongxing Road
Nantong, Jiangsu 226007
China

NOV 2 7 2009

Re: K093359
Trade/Device Name: 1103 Digital Blood Pressure Monitor, Model ID 1103 and
1133 Digital Blood Pressure Monitor, Model ID 1133
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN
Dated: October 19, 2009
Received: October 28, 2009

Dear Janusun 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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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

Enclosure

Attachment 1

Indications for use

510(k) Number (if known): K093359

Device Name: Littledoctor Digital BP Monitor LD 1103 and LD 1133

Indications for Use:

The subjects are intended to be used for measuring blood pressure(systolic and diastolic pressure) and pulse rate, for adult, by oscillometric method, upon the upper arm and at home or in hospital.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093359