K041400

FORTIFIER INTERNATIONAL CO., LTD.

No. 45, Jung Shan 1st Road, Jung Shan Chiu, 203,
Keelung, Taiwan, ROC
Tel: 886-2-24231179 Fax: 886-2-24269170
E-mail: ficl@ms8.hinet.net

AUG 2 4 2004

" 510(k) SUMMARY "

Submitter's Name: ***FORTIFIER International Co., Ltd.***

No. 45, Jung Shan 1st Road, Jung Shan Chiu, 203,
Keelung, Taiwan, ROC
Tel: 886-2-24231179 Fax: 886-2-24269170
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Date summary prepared: May 15, 2004

Device Name:

Proprietary Name: *FORTIFIER Digital Wrist Blood Pressure Monitor, LF-01*

Common or Usual Name: NONINVASIVE BLOOD PRESSURE MEASUREMENT SYSTEM

Classification Name: *Blood Pressure Monitor*, Class II,
21 CFR *870.1130*

Indications for Use:

The device is a noninvasive blood pressure measurement system intended to measure the systolic and diastolic blood pressures and pulse rate of an adult individual, over age 18, at home by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to be 5.25" – 7.75".

Description of the device:

FORTIFIER Digital Wrist Blood Pressure Monitor, LF-01 uses the Oscillometric method to measure the blood pressure. The Oscillometric method is adopted clinically to measure the blood pressure recently. It is not needed to use the stethoscope, as in the traditional measuring method, to monitor the Korotkov sound when deciding the systolic or diastolic pressure. The Oscillometric method senses the vibrating signal via the closed air pipe system and utilizes the microcomputer to automatically sense the characteristics of the pulse signal. Through simple calculation, clinically proven, the reading can reflect the accurate real blood pressure, and the systolic pressure is defined as the pressure when the cuff pressure oscillating amplitude begins to increase and the diastolic pressure as the pressure when the cuff pressure oscillating amplitude stops decreasing.

K021105

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Performance Testing:

Electric Safety Requirement Test Report of EN 60601-1:1990 & EN 1060-1/ EN1060-3, and EMC test report of EN 60601-1-2 (*EN 55011:1991* and *EN 61000-4-2:1995*)

ANSI/AAMI SP10-1992 Electronic or Automated Sphygmomanometers

Legally marketed device for substantial equivalence comparison:

Eikon Automatic Digital Blood Pressure Monitor, HD-400M **(K021239)**

Summary for substantial equivalence comparison:

Same characteristics: intended use, technological characteristics, power supply, display, measuring range, accuracy, operating and storage environments.

Different characteristics: memory, dimensions, and weight.

1. As we can understand, the memory feature is to memorize the measurement data taken previously and is related to the usage convenience, not to raise any safety or effectiveness hazard.

2. The differences between dimensions and weight are related to the designing aspects. These differences are not to raise any safety or effectiveness aspect.

They are decided to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2004

Dr. Jen Ke-Min.
Fortifier International, Co., Ltd.
c/o ROC Chinese-European Industrial
No. 58, Fu-Chiun St.
Hsin-Chu City
CHINA (Taiwan) 300

Re: K041400
Trade Name: FORTIFIER Digital Wrist Blood Pressure Monitor, LF-01
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: May 15, 2004
Received: May 26, 2004

Dear Dr. Ke-Min:

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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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

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Applicant: ***FORTIFIER International Co., Ltd..***

510(k) Number (if known): K041400

Device Name: *Digital Wrist Blood Pressure Monitor, LF-01*

- *Indications for use:*

The device is a noninvasive blood pressure measurement system intended to measure the systolic and diastolic blood pressures and pulse rate of an adult individual, over age 18, at home by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to be 5.25" – 7.75".

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (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)

Neil R Ogden for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041400