5. 510(k) SUMMARY

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

The Assigned 510(k) number is K060925.

MAY - 9 2006

Submitter's Identification:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

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Date Prepared: March 31, 2006

Contact Person:

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Proprietary Name of the Device:

ACON™ Automatic Blood Pressure Monitor Kit

Common Name:

System, Measurement, Blood-Pressure, Non-Invasive

Classification Name:

Class II §870.1130 Noninvasive Blood Pressure Measurement System
(To be manufactured and marketed for consumer home use)

Predicate Device:

OMRON Automatic Blood Pressure Monitor, Model # HEM-711AC
OMRON Healthcare, Inc., located at 300 Lakeview Parkway, Vernon Hills, IL 60061, USA.
510(k) Number: K930798

Description:

The ACON Automatic Blood Pressure Monitor (BPM) Kit consists of an oscillometer assembly that measures blood pressure oscillometrically. This BPM comes with a standard & a large arm cuff. The BPM is powered by either four AA batteries or an optional AC adapter. Before measuring, the user fits the end of the cuff through a D-ring and secures it by the Velcro strap around the upper arm. The position of the arm cuff should be leveled with user's heart. Once fastened, the user turns on the BPM to initiate a self-checking program. The cuff is automatically inflated by the pump only when the BPM passes the self-check and the "Err" sign is not shown on the monitor. While inflating, the monitor displays upward numbers and arrows to signify that the cuff is slowly inflating. After reaching the appropriate level, the pumping action stops and the monitor displays downward numbers and arrows to signify that the cuff is slowly deflating. During this time, a heart-shaped icon also appears on the right hand side of the monitor together with the beeping sounds, indicating the heart rate is also being measured. Once the monitoring has completed, the LCD screen displays the following measurements from top to bottom: systolic blood pressure (SYS), diastolic blood pressure (DIA), and pulse rate (P) to the user.

Intended Use:

The ACON Automatic Blood Pressure Monitor is a fully automatic blood pressure monitor that measures systolic blood pressure, diastolic blood pressure and pulse rate. It is intended to be sold over-the-counter for home use.

Technological Characteristics:

Feature	Technical Specification
Measurement Area	Upper arm
Measurement Technology	Oscillometry
Measurement Range	Blood Pressure (SYS and DIA): 30 to 280 mmHg (4.00-37.33kPa); Pulse Rate (P): 40 to 200 beats per minute
Accuracy	Blood Pressure (SYS and DIA): ± 3 mmHg (0.40kPa); Pulse Rate (P): ± 5 %
Measurement Resolution (DIA/SYS)	1 mmHg (0.13kPa)
Cuff Pressure Display Range	0-299 mmHg (0-39.86kPa)
Inflation Method	Automatic by electric pump
Deflation Method	Automatic pressure release valve
Rapid Pressure Release Method	Automatic exhaust valve
Display	Liquid Crystal Display (LCD)
Memory	Automatically stores the last 36 measurements taken
Operating Temperature	50 to 104°F
Operating Humidity	10 to 85% RH
Storage Temperature	-4 to 122°F
Storage Humidity	10 to 95% RH

Arm Size and Cuff Circumference	Standard Cuff: for 7"-13" upper arm circumference; Large Cuff: for 13"-18" upper arm circumference
Power Source	4 "AA" 1.5V alkaline (LR6) or equivalent battery; 6V 500mA or 600mA output AC Adapter
Battery Life	Approximately 300 uses
Size	4.6" (W) x 4.7" (L) x 2.4" (H)
Weight	19.7 oz (with batteries and Standard Cuff) 20.3 oz (with batteries and Large Cuff)

Comparison to Predicate Devices:

The ACON Automatic Blood Pressure Monitor Kit is substantially equivalent to the OMRON Automatic Blood Pressure Monitor, Model #HEM-711AC, K930798.

The blood pressure arm cuffs included in the ACON™ Automatic Blood Pressure Monitor Kit are exactly the same as a FDA-cleared KTJ-20C™ Blood Pressure Cuff (K010686), manufactured by Golden Horse Medical Equipment (WUXI) Co, LTD.

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

Guidance documents included the "FDA Guidance on the Content of Premarket Notification 510(k) Submissions for Non-Invasive Blood Pressure (NIBP) Monitor" and "FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Compliance to applicable voluntary standards includes ANSI/AAMI SP-10:2002/A1:2003, as well as AAMI 60601-2-30:1999 requirements.

Laboratory Testing:

The performance characteristics of the ACON™ Automatic Blood Pressure Monitor Kit were verified by many tests including pressure accuracy test, pulse accuracy test, repeatability test, operation condition test including temperature, humidity and ambient pressure tests, battery condition test, storage condition test, AC adaptor test, measurement time test, power consumption test, temperature compensation test, software validation test and electromagnetic compatibility and electrical safety test.

Discussion of Clinical Tests Performed:

Consumer studies were conducted using the ACON™ Automatic Blood Pressure Monitor Kit. Consumer study data are presented and the mean deviation and standard deviation between the ACON and OMRON Blood Pressure Monitors and between the ACON Blood Pressure Monitor and a Mercury Sphygmomanometer per ACON consumer study protocol for Blood Pressure Monitor are compared. Study results indicate that the non-professional, inexperienced lay

persons were able to obtain comparable blood pressure and pulse rate readings when using the ACON™ Automatic Blood Pressure Monitor Kit and a legally marketed OMRON Automatic Blood Pressure Monitor, Model #HEM-711AC (K930798). In addition, the participated lay persons also satisfied with the ease of following the "Instructions for Use" section in the Instruction Manual as well as the performance of the BPM.

Conclusion:

The laboratory testing and consumer study results demonstrated that the ACON™ Automatic Blood Pressure Monitor is safe, accurate and easy-to-use. It is also demonstrated that the ACON™ Automatic Blood Pressure Monitor is substantially equivalent to the OMRON Automatic Blood Pressure Monitor, Model #HEM-711AC, currently sold on the U.S. market (K930798).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2006

ACON Laboratories, Inc.
c/o Edward Tung, Ph. D.
Vice President, Regulatory Affairs
4108 Sorrento Valley Boulevard
San Diego, CA 92121

Re: K060925
Trade Name: ACON Automatic Blood Pressure Monitor Kit (Model OB11-111) and
ACON Automatic Blood Pressure Monitor Kit with AC Adapter (Model OB11-112)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: March 31, 2006
Received: April 4, 2006

Dear Dr. Tung:

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 (301) 443-6597 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

4. INDICATIONS FOR USE

510(k) Number (if known): K060925

Device Name: ACON™ Automatic Blood Pressure Monitor Kit

Indications for Use:

The ACON Automatic Blood Pressure Monitor is a fully automatic blood pressure monitor that measures systolic blood pressure (SYS), diastolic blood pressure (DIA) and pulse rate (P). It is intended to be sold over-the-counter for home use.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060925