CalHealth, Inc.
Home of MDMouse™
7545 Irvine Center Drive, Suite 200 Irvine, California 92618 Office: (949) 623-8662 Fax: (949) 623-8305

"510(k) Summary"

JAN - 7 2009

DATE OF SUBMISSION: June 30, 2008

SUBMITTER:

CalHealth, Inc.
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Irvine, CA 92618,
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TEL: (949) 623-8662 FAX: (949) 623-8305

ESTABLISHMENT REGISTRATION NO: 3006985801

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TRADE NAME: Finger Blood Pressure Monitor, MDMouse

COMMON/USUAL NAME: Blood Pressure Monitor

CLASSIFICATION NAME: Non-Invasive Blood-Pressure Measurement System (21CFR 870.1130)

PRODUCT CODE: DXN

CLASSIFICATION PANEL: CARDIOVASCULAR

PREDICATED DEVICE: Omron Digital Finger Blood Pressure Monitor (K894563)

INTENDED USE: The CalHealth Finger Blood Pressure Monitor, MDMouse is noninvasive blood pressure measurement systems 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 left index finger.
The cuff circumference is designed for Left Index Finger circumference: 1.5' ~ 3.5' (3.7 ~8.8 cm) for finger type.

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Description of the new device: (Same as the predicate devices)

CalHealth Finger Blood Pressure Monitor, MDMouse 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, 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.

Technological Characteristics of our new device compared to the predicate device:

The technological characteristics of CalHealth Finger Blood Pressure Monitor, MDMouse are substantially equivalent to Omron Digital Finger Blood Pressure Monitor (K894563). The main difference is the subject device has the functions for connects to the PC by using USB cable for data transmission.

Thus there are substantially equivalent.

Test Summary:

1. **ELECTRIC SAFETY, EMC and FCC test reports,**

General safety	*IEC/EN 60601-1:1990+A1+A2+A11+A12+A13*	***PASS***
	EN 1060-1:1995, EN 1060-3:1997	***PASS***
EMC conformity	*IEC/EN 60601-1-2: 1993*	***PASS***
FCC conformity	*ANSI C63.4: 2003*	***PASS***

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2. **WOVEN COTTON SHEETING:**

   Uses the 510K Blood-Pressure Cuff: YA HORNG Blood-Pressure Cuff (K051539).

3. **PERFORMANCE & CLINICAL TEST**

   AAMI / ANSI SP10:
   Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance Version 1; Final

CalHealth, Inc. believes this information and referred document to be sufficient for the FDA to find our proposed device substantially equivalent to the predicate product and other products currently in distribution.

Dr. Jen, Ke-Min
official correspondent for
CalHealth, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2009

CalHealth, Inc.
c/o Dr. Jen, Ke-Min
Roc Chinese-European Industrial Research Society
No. 58, Fu-Chiun St.
Hsin-Chu City, 30067
Taiwan, ROC

Re: K081924
Trade/Device Name: Finger Blood Pressure Monitor, MDMouse
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: December 24, 2008
Received: January 5, 2009

Dear Dr. Jen:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

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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Home of MDMouse™

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Indications for Use

510(k) Number: K081924

Device Name: CalHealth, Inc.
Finger Blood Pressure Monitor, MDMouse

- ***Indications for use:***

The CalHealth Finger Blood Pressure Monitor, MDMouse is noninvasive blood pressure measurement systems 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 left index finger.
The cuff circumference is designed for Left Index Finger circumference: 1.5' ~ 3.5' (3.7 ~8.8 cm) for finger type.

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)

Donna R. Vechnes

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081924