



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

APR 29 2010

Harvard Medical Devices Ltd.  
c/o Mr. Martin Ma  
Unit 1301-2, 13<sup>th</sup> Floor, Railway Plaza  
39 Chatam Road South  
Tsimshatsui, Kowloon  
Hong Kong

Re: K092558  
Trade Name: Wrist Type Blood Pressure Monitor, HMBPM-005/Kinetik Branded BPM2  
Series  
Regulation Number: 21 CFR 870.1130  
Regulation Name: Non-invasive Blood Pressure Monitors  
Regulatory Class: Class II (two)  
Product Code: DXN  
Dated: undated  
Received: February 26, 2010

Dear Mr. Ma:

This letter corrects our substantially equivalent letter of March 17, 2010.

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.

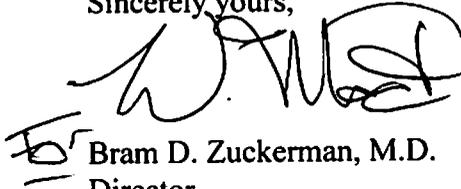
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style with a large initial "B".

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indication for Use

510(K) Number (if known): K092558

Device Name:

Wrist Type Blood Pressure Monitor, HMBPM-005/Kinetik Branded BPM2 Series

Indication For Use

Wrist Type Blood Pressure Monitor is for use at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. The theoretical range of cuff circumference is limited to 14-19.5cm.

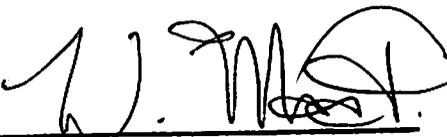
Prescription Use \_\_\_\_\_ AND/OR Over-The-Counter Use YES

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-COUNTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Signature)  
Division of Cardiovascular Devices  
510(k) Number K092558

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