 K080656

510(k) Summary

EXHIBIT #1

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: January 11, 2008

FEB 13 2009

1. Submitter:

Name:	HuBDIC Co., Ltd. 195-42, Anyang 7-dong, Manan-gu, Anyang-si, Gyeonggi-do, Korea
Contact:	In-Young An Phone +82-31-441-8671 Fax +82-31-442-4994

2. Device:

Proprietary Name:	Duo-Max Blood Pressure and Glucose Monitor, Model HMF-100
Common Name:	Blood Pressure Monitor, Blood Glucose Monitor, Blood glucose test strip and quality control material
Classification Name:	System, test, blood glucose, over the counter Glucose oxidase, glucose Single (specified) analyte controls System, measurement, blood pressure, non invasive
Classification:	21 CFR 862.1345
Product Code:	NBW, CGA, JJX, DXN

3. Predicate Device:

Blood Glucose and Blood Pressure Monitor System, Model BGP-100
Sein Electronics Co., Ltd K052108
Infopia Glucolab™ Blood Glucose Monitoring System K051285

4. Description:

HuBDIC's Duo- Max Blood Pressure and Glucose Monitor System, Model HMF-100 combines the function of a blood pressure meter and a blood glucose monitoring system in one unit. Supplies with the meter are test strips, lancets, Lancing device, storage case, batteries and log book.

HMF-100 adopts the wrist type cuff for blood pressure meter part. The cuff and control unit are combined into a single wrist-mounted assembly. The user interface pane has power switch, timer switch, memory switch for blood pressure meter part and LCD for displaying the systolic blood pressure, diastolic blood pressure, pulse rate, date and time. This device has the memory function that permits memory and display of the 180 most recent measurement results.

5. Indications for use:

The Duo-Max Blood pressure and Glucose Monitor, Model HMF-100 consists of a meter with wrist cuff and test strips. The system is intended for use in the quantitative measurement of glucose in whole blood taken from the fingertip. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes mellitus, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. It is not intended for use on neonates. Also the system measures systolic and diastolic blood pressure and pulse rate from adult's wrist in the home care environment. The device employs a wrist cuff and the oscillometric metric method of measurement.

6. Comparison of Technological Characteristics with Predicate:

The Duo-Max Blood Pressure and Glucose Monitor, Model HMF-100 has the same general design and performance characteristics as the predicate device from Sein. The main difference is the physical size, shape and weight as seen below:

Item	Duo-Max Blood Pressure and Glucose Monitor, model HMF-100	Sein, Blood Glucose and Blood Pressure Monitor System, Model BGP-100
Pulse Rate	20 ~ 199 pulse/min	40 ~ 199 pulse/min
Number of Readings stored in Memory	180 times (Blood Pressure Part) 270 times (Blood Glucose Part)	60 times (Blood Pressure Part) 150 times (Blood Glucose Part)
Dimension	64(W) x 84(W) x 31(H)(mm)	62(W) x 83(W) x 33(H)(mm)
Weight	163g	192g

7. Performance Data:

In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards including ANSI/AAMI SP-10, IEC 60601-1 and IEC 60601-1-2 requirements.

The Blood Pressure and Glucose Monitor, Model HMF-100 tested and met all relevant requirements of the aforementioned tests.

8. Conclusion:

We have demonstrated that the Blood Pressure and Glucose Monitor, Model HMF-100 is as safe and effective as the predicate devices based on our performance testing results as well as with the risk analysis supplied with this submission.

This submitter concludes that the Blood Pressure and Glucose Monitor, Model HMF-100 is therefore substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

HuBDIC Co. Ltd.
c/o Maria Griffin, MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

FEB 1 3 2009

Re: k080636
Trade Name: Duo-Max Blood Pressure and Glucose Monitor, Model HMF-100
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA, DXN, JJX
Dated: January 30, 2009
Received: February 2, 2009

Dear Ms. Griffin:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): k080636

Device Name: Blood Pressure and Glucose Monitor, Duo-Max™ (Model HMF-100)

Indication For Use:

The Blood pressure and glucose monitor, Duo-Max™ consists of a meter with wrist cuff and glucose test strips. The glucose test system is intended for use in the quantitative measurement of glucose in capillary whole blood taken from the fingertip, dorsal hand, ventral palm, upper arm, forearm, calf and thigh. Glucose testing is done outside the body (In Vitro diabetes mellitus, or in clinical settings by healthcare professionals. Glucose testing system is not to be used for the diagnosis or screening of diabetes. It is not intended for use on neonates. Also the blood pressure test system measures systolic and diastolic blood pressure and pulse rate from adult's wrist in the home care environment. The device employs a wrist cuff and the oscillomentric metric method of measurement.

Prescription Use _____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use __v__ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K080636