K091168

510(k) Summary **Attachment #4**

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.
The assigned 510(K) Number is not applicable.

MAY 27 2010

Date: May 21, 2010

1. Submitter:

Submitted by:	Infopia Co.,ltd. #891, Hogye-dong, Dongan-Gu Anyang, Kyunggi 431-080, Korea Phone: 82-31-460-0400 Fax: 82-31-0401
Contact:	Bryan Oh Phone: 1-321-267-9911 Fax: 1-321-267-5582

2. Device:

Propriety Name	Glucophone™ Blood Glucose Monitoring System
Common Name	Blood Glucose Test System
Classification Name:	System, test, blood glucose, over the counter Glucose Oxidase Single (specified) analyte controls
Classification:	Class II, 21 CFR 862.1345,
Product Code:	NBW, CGA, JJX

3. Predicate Device:

GlucoPack™ Blood Glucose Monitoring System(HealthPia America Corp.)
K052469
GlucoLab™ Blood Glucose Monitoring System(Infopia co., Ltd.)
K051285

4. Description:

The Glucophone™ Meter device combined with Cell Phone (Motorola v3) is used along with the Glucophone™ Test Strip to measure the glucose level in capillary whole blood.

Test Principle

The principle of the test relies upon a specific type of glucose in the blood sample, the glucose oxidase reacts to electrodes in the test strip. The test strip employs an electrochemical signal generating an electrical current that will stimulate a chemical reaction. This reaction is measured by the Meter and displayed as your blood glucose result.

5. Indications for use:

Glucophone™ Blood Glucose Testing System is for the quantitative measurement of the concentration of glucose in capillary whole blood that can be taken from the fingertip, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh by diabetic patients or healthcare professionals in the home and in clinical setting. Glucophone™ Blood Glucose Testing System is for testing outside the body (in vitro diagnostic use only). GlucoPhone™ Blood glucose Testing system is for use with a cellular phone. GlucoPhone™ Blood glucose Testing system is not for neonatal use and not for diagnosis or screening of diabetes. Alternate site testing is for use during times of steady state.

6. Comparison of Technological Characteristics with Predicate:

The technological characteristics of the new device (Glucophone™) in comparison to two predicate devices (GlucoPack™, GlucoLab™):

The modified Glucophone™ device has the same technological characteristics as the current legally marketed predicate devices: 1. same in the meter device technology with GlucoPack™ Glucose Monitoring System (K052469) By HealthPia America Corp. and 2. same in the strip technology with GlucoLab™ Blood Glucose Monitoring System (K051285) By Infopia co., Ltd..

7. Performance Data:

Clinical: The clinical performance evaluation using the Glucophone™ Blood Glucose Monitoring System components were conducted for the purpose of validating consumer use and professional accuracy. Test results showed substantial equivalence.

Non-clinical: Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the Glucophone™ Blood Glucose Monitoring System with respect to two predicate devices. Testing involved the verification

of software requirement specifications, product requirement specifications and user interface requirement specifications from the risk analysis. The device passed all of the tests based on pre-determined Pass/Fail criteria.

8. Conclusion

The data from the clinical and non clinical tests show that the Glucophone™ Blood Glucose Monitoring System is as safe and effective as the legally marketed predicate devices, the GlucoPack™ and GlucoLab™.

Therefore we conclude that the Glucophone™ Blood Glucose Monitoring System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Infopia Co., Ltd.
C/O Maria Griffin
MDI Consultants, Inc.
55 Northern Blvd. Suite 200
Great Neck, NY 11021

MAY 27 2010

Re: k091168
Trade/Device Name: Glucophone™ Blood Glucose Testing System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: May 21, 2010
Received: May 24, 2010

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indication for Use

510(k) Number (if known): K091168

Device Name: Glucophone™ Blood Glucose Testing System

Indication For Use:

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Prescription Use _____ And/Or Over the Counter Use X .
(21 CFR Part 801 Subpart D) (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 Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k)