510(k) Summary
(k113192)

JUL 13 2012

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

Date: 07/09/2012

1. Submitter:

Name:	Infopia Co., Ltd 891, Hogye-Dong, Dongan-Gu, Anyang, Kyunggi, Republic of Korea 431-080
Contact:	Youngju Park Phone +82 31 460 0300 Fax +82 31 460 0401

2. Submission Correspondent:

Priscilla Chung
LK Consulting Group
951 Starbuck St. Unit J,
Fullerton, CA 92833
Phone: 714-844-2612 Fax: 714-409-3357
Email: info@lkconsultinggroup.com

3. Device:

Proprietary Name:	Healthpro™ 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
Classification Product Code:	NBW
Subsequent Product Codes	CGA, JJX

4. Predicate Device:

GLUCOLAB Auto-coding (IGM-0022)
Infopia Co., Ltd.

K091157

5. Description:

The Healthpro™ Blood Glucose Monitoring System consists of the meter, test strips and control solutions (low, normal and high levels), a lancing device and sterile lancets (sold separately; accessory). The blood glucose test system is an in vitro diagnostic device designed for measuring the concentration of glucose in whole blood sample by means of an electrical current produced in the test strip and sent to the meter for measurement.

6. Indications for use:

The Healthpro™ Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh. The Healthpro™ Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

The Healthpro™ Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Healthpro™ Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady–state times (when glucose is not changing rapidly).

The Healthpro™ test strips are for use with the Healthpro™ meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh.

The Healthpro™ control solutions are for use with the Healthpro™ meter and test strips to check that the meter and test strips are working together properly and that the test as a quality control checks to verify the accuracy of blood glucose test results.

7. Technological Characteristics:

The Healthpro™ Blood Glucose Monitoring System has the same fundamental scientific technology as the GLUCOLAB Auto-coding (IGM-0022) predicate device, K091157. But the performance characteristic between them shows slight difference.

8. Performance Data:

The Healthpro™ Blood Glucose Monitoring System was performed in accordance with ISO 15197:2003. The clinical performance evaluation testing included system accuracy, user performance and alternative-site blood glucose measurement. The non-clinical performance evaluations are validated and tested, it conducted to establish the performance, functionality and reliability characteristics of the Healthpro™ Blood Glucose Monitoring System. The device passed all of the tests based on pre-determined Pass/Fail criteria.

Disinfectant CaviWipes with the EPA registration number of 46781-8 has been validated demonstrating complete inactivation of live virus of use with the meter and the reusable lancing device. There was also no change in performance or in the external materials of the meter and the lancing device after 1,095 cleaning/disinfection cycles designed to simulate 3 years of device use.

9. Conclusions:

Infopia Co., Ltd. concludes that the Healthpro™ Blood Glucose Monitoring System is safe and effective also, substantially equivalent to predicate device, GLUCOLAB Auto-coding (IGM-0022), K091157.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Infopia Co., Ltd.
c/o Priscilla Chung
Regulatory Affairs Consulting
LK Consulting Group
951 Starbuck St. Unit J
Fullerton, CA 92833

JUL 13 2012

Re: k113192
Trade/Device Name: Healthpro Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, LFR, JJX
Dated: June 6, 2012
Received: June 7, 2012

Dear Ms. Chung:

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).

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

Enclosure

Indications for Use

510(k) Number K _____

Device Name: Healthpro™ Blood Glucose Monitoring System

Indication for use:

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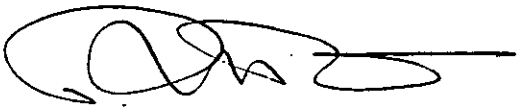
Prescription Use_____ AND/OR Over-The-Counter Use_✓_____
(Part 21CFR801 Subpart D) (Part 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



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

510(k) k113192