510(K) Summary
(K090405)

DEC - 1 2009

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

1. Application date: 02/17/09

2. Submitter Information

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4. Trade name: LipidPro™ system, LipidPro™ Total cholesterol (TC) control solution, LipidPro™ High density lipoprotein cholesterol (HDL-C) control solution, LipidPro™ Triglyceride (TG) control solution and LipidPro™ Glucose control solution

5. Classification name:

Total cholesterol test system (21 CFR Part 862.1175, CHH)

Lipoprotein test system (21 CFR Part 862.1475, LBR)

Triglyceride test system (21 CFR Part 862.1705, JGY)

Glucose test system (21 CFR Part 862.1345, NBW, CGA)

Quality control material (assayed and unassayed) (21 CFR Part 862.1660, JJX)

6. Predicate

- Predicate for the Lipid profile test system

  PTS PANELS Lipid Panel Test Strips (K023558) / Polymer Technology Systems, Inc.

- Predicate for the glucose test system

  Evolution™ Blood Glucose Test System (K072369) / HMD Biomedical LLC.

- Predicate for the control solution

PTS Panels Multi-Chemistry Controls (K022401) / Polymer Technology Systems, Inc.

7. Device Description

The LipidPro™ system is a device which combines measuring systems for total cholesterol, high density lipoprotein cholesterol, low density lipoprotein cholesterol and triglyceride, and a blood glucose monitoring system into one convenient device. The glucose monitoring system function of the device utilizes Infopia's Evolution™ monitoring system cleared under K072369.

The LipidPro™ system consists of a meter, five types of test strips, and four types of control solutions. The five types of the test strips are for total cholesterol (TC), high density lipoprotein cholesterol (HDL-C), triglyceride (TG),a lipid profile (which combines TC, HDL-C, TG tests) and glucose test respectively. The four types of the control solutions are for total cholesterol (TC), high density lipoprotein cholesterol (HDL-C), triglyceride (TG) and glucose test respectively.

LDL value is calculated from TC, HDL-C, and TG values using the following numerical formula. When TG is over 350 mg/dL, LDL is not calculated.

$$LDL=TC-HDL-(TG/5)$$

LipidPro™ glucose test system is identical to the EVOLUTION™ glucose test system cleared under K072369. LipidPro™ glucose test strip is the same as the EVOLUTION™ glucose test strip except the cover printing design. Their size and components are the same. LipidPro™ glucose test meter is identical to the EVOLUTION™ glucose test meter except the external design and having a lipid profile (TC/TG/HDL-C) test part on the other side of the meter. This does not affect to the safety and effectiveness for glucose test and data.

The test range of LipidPro™ system is 100-400mg/dL for total cholesterol, 25-80 mg/dL for HDL-cholesterol, 70-600 mg/dL for Triglyceride and 20-600mg/dL for glucose. LDL cholesterol should be estimated from measurement of total cholesterol, HDL cholesterol and triglycerides.

LipidPro™ system has two kinds of test principle according to test items: one for glucose and the other for a lipid profile (TC, HDL-C, and TG).

Lipid profile test results are based on reading reflection density. When the blood is applied, the color changes in test area through an enzyme reaction. The meter records this change in color and converts the measurement signal to the displayed result using the data previously entered via the code. The deeper the color is, the higher the lipid level is.

Glucose in the blood sample will react to the electrodes in the glucose test strip, generating an electrical current that will stimulate a chemical reaction. This reaction is measured by LipidPro™ meter and displayed as your blood glucose result.

8. Intended Use

LipidPro™ system is intended for in home (self-testing) or health care professionals and for testing outside the body (in vitro diagnostic use only). LipidPro™ system which consists of meter and test strips, measures total cholesterol (TC), high density lipoprotein cholesterol (HDL-C), triglyceride (TG) and glucose in capillary whole blood.

Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis and various liver and renal diseases. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders. Calculated LDL-cholesterol values are reported only when triglycerides are $\leq$ 350 mg/dL; when triglycerides are > 350 mg/dL, calculated LDL-cholesterol are not reported.

Glucose measurement 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 health care professionals as an aid in the management of diabetes. Glucose measurement is not to be used for the diagnosis of or screening for diabetes or for neonatal use. Alternate site testing should be done during steady- state times when glucose is not changing rapidly.

LipidPro™ Total Cholesterol control solution, HDL-cholesterol control solution, Triglyceride control solution, and Glucose control solution are used to test the precision of the LipidPro™ system and to detect systematic analytic deviations that may arise from reagent or analytical variation and they are for testing outside the body (in vitro diagnostic use only.) LipidPro™ control solutions are intended for in home and health care professionals use.

9. Comparison of Technological Characteristics with Predicate

The LipidPro™ system has the same technological characteristics as the current legally marketed predicate device, PTS PANELS Lipid Panel Test Strips (K023558), Evolution™ Blood Glucose Test System (K072369) and PTS Panels Multi-Chemistry Controls (K022401).

Similarities and Differences of the Lipid profile measuring system		
Item	LipidPro™ lipid measuring system	PTS PANELS Lipid Panel Test Strips (k023558)
Detection method	Spectrophotometry	Spectrophotometry
Enzyme	TC: Cholesterol esterase, Cholesterol oxidase, Peroxidase HDL-C: Cholesterol esterase, Cholesterol oxidase, Peroxidase TG: Lipase lipoprotein, Glycerol kinase, Glycerol-3-Phosphate Oxidase, Peroxidase	TC: Cholesterol esterase, Cholesterol oxidase, Peroxidase HDL-C: Cholesterol esterase, Cholesterol oxidase, Peroxidase TG: Lipase lipoprotein, Glycerol kinase, Glycerol-3-Phosphate Oxidase, Peroxidase
Color Fixatives	TC, HDL-C, TG: 4-aminoantipyrine Substituted aniline derivatives	TC, HDL-C: 4-aminoantipyrine Substituted aniline derivatives TG: 4-aminoantipyrine N,N-disubstituted aniline
Coding	Auto-coding by the RFID tag	MEMO Chip
Sample type	Capillary whole blood	Capillary whole blood Venous whole blood
Humidity range	10 ~ 90%	20 ~ 80%
Power supply	2 AAA 1.5 Volt alkaline	2 AAA 1.5 Volt alkaline
Battery lifetime	1000tests	300tests
Test range	TC : 100-400 mg/dL HDL-C: 25-80 mg/dL TG: 70-600 mg/dL	TC : 100-400 mg/dL HDL-C: 25-85 mg/dL TG: 50-500 mg/dL
Hematocrit range	TC, HDL-C, TG: 30 ~55%	TC: 30~50% HDL-C: 30~45% TG: 15~55%
Test time	1-2 minutes	1-2 minutes
Sample volume	5 $\mu\ell$	15 $\mu\ell$
Temperature range	18-30°C (64~86°F)	18-35°C (64.4-95°F)

Similarities and Differences of the Lipid profile measuring system		
Item	LipidPro™ lipid measuring system	PTS PANELS Lipid Panel Test Strips (k023558)
Size L x W x H (cm)	10.9 X 6.04 X 2.29	13.97 X 7.62 X 2.54
Weight	77.5 g	121.9 g

Similarities and Differences of the Blood Glucose System		
Item	LipidPro™ glucose measuring system	Evolution glucose system (k072369)
Detection method	Amperometry	Amperometry
Enzyme	Glucose Oxidase	Glucose Oxidase
Mediator	Hexaammineruthenium(III)Chloride	Hexaammineruthenium(III)Chloride
Electrode	Carbon electrode	Carbon electrode
Coding	Auto-coding by the color bar	Auto-coding by the color bar
Sample type	Capillary whole blood	Capillary whole blood
Humidity range	10 ~ 90%	20 ~ 80%
Power supply	2 AAA 1.5 Volt alkaline	3V Li battery (CR2032×2)
Battery lifetime	1000 tests	1 years
Test range	20 ~ 600 mg/dL	20 ~ 600 mg/dL
Hematocrit range	30 ~55%	20~60%
Test time	3 seconds	3 seconds
Sample volume	0.3 uL	0.3 uL
Temperature range	18-30°C (64~86°F)	10 ~ 40° C(50 ~ 104° F)
Memory capability	200 tests	7, 14, 21-day average and 365 tests in the memory
Size L x W x H (cm)	10.9 X 6.04 X 2.29	7.6 X 5.6 X 1.8
Weight	77.5 g	45g

Similarities and Differences of the control solution		
Item	LipidPro™ Control Solution	PTS panels multi-chemistry Control Solution (k022401)
Indication for use	LipidPro™ Total Cholesterol control solution, HDL-cholesterol control solution, Triglyceride control solution, and Glucose control solution are used to test the precision of the LipidPro™ system and to detect systematic analytic deviations that may arise from reagent or analytical variation and they are for testing outside the body (in vitro diagnostic use only.)	The PTS PANELS Multi-Chemistry Controls are intended for use on the BioScanner2000 and CardioChek brand instruments to estimate precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation and are intended for use by healthcare professionals in both physicians' offices and in acute and convalescent care facility bedside testing as well as consumers at home.
Analyte	Glucose TC: Total Cholesterol HDL-C: HDL-Cholesterol TG: Triglyceride	Cholesterol, Triglyceride, Glucose, and Ketones
Number of levels	TC: 2 Levels (Normal, Abnormal) HDL-C: 2 Levels (Normal, Abnormal) TG: 2 Levels (Normal, Abnormal)	2 Levels (Level 1, Level 2)
Container	Bottle	Bottle
Color	Clear	Clear
Temperature range	8~30℃(46~86°F)	20~30℃(68~86°F)
Fill volume	1.0mL	1.5mL
Matrix	TC: Cholesterol, insert ingredients HDL-C: Cholesterol, insert ingredients TG: Triglyceride, insert ingredients	Glucose, Glycerol, Cholesterol, DL-β-Hydroxybutyric Acid, MIT(methyl isothazoldone) and insert ingredients
Target range	The expected range is printed on the Control Solution Range Card.	The expected range is printed on the Quality Control Solution Range Card.

10. Performance Data

Clinical: The clinical performance evaluation using the LipidPro™ system was conducted for the purpose of validating the TC, HDL-C, LDL-C, TG, and Glucose measuring 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 LipidPro™ system with respect to the predicate device. Pass or fail criteria were based on the specifications cleared for the predicate device and results showed substantial equivalence.

11. Conclusion

The conclusion drawn from the clinical and the non clinical tests is that the LipidPro™ system is as safe, as effective, and performs as well as the legally marketed predicate device, the PTS PANELS™.

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 Ms. Priscilla Chung
Krodent DBA TMS
13340 E. Firestone Blvd., Suite J
Santa Fe Springs, CA 90670

DEC - 1 2009

Re: k090405
Trade Name: LipidPro™ system (ILM-0001A), LipidPro™ Total cholesterol (TC) control solution, LipidPro™ High density lipoprotein cholesterol (HDL-C) control solution, LipidPro™ Triglyceride (TG) control solution and LipidPro™ glucose control solution
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System.
Regulatory Class: Class II
Product Codes: CGA, NBW, JGY, CHH, LBR, JJX
Dated: November 18, 2009
Received: November 19, 2009

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 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): K090405

Device Name: LipidPro™ system (ILM-0001A), LipidPro™ Total cholesterol (TC) control solution, LipidPro™ High density lipoprotein cholesterol (HDL-C) control solution, LipidPro™ Triglyceride (TG) control solution and LipidPro™ Glucose control solution

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Prescription Use ___X___ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use ___X___ (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) K090405

Indication for Use

510(k) Number (if known): K090405

Device Name: LipidPro™ system (ILM-0001A), LipidPro™ Total cholesterol (TC) control solution, LipidPro™ High density lipoprotein cholesterol (HDL-C) control solution, LipidPro™ Triglyceride (TG) control solution and LipidPro™ Glucose control solution

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Prescription Use ___X___ 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 C. Benson

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Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K090405