FEB 6 2007

K062567

Exhibit 1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. **Submitter's Identification:**

BIONIME CORPORRATION
NO 694, RENHUA ROAD, DALI CITY, TAICHUNG COUNTY, TAIWAN 412
Contact Person: Patrick Hsieh
Phone Number: 886-4-24951268
FAX Number: 886-4-24952568

Date Summary Prepared: December 18, 2006

2. **Name of the Device: Rightest Blood Glucose Monitoring System**

3. **Common or Usual Name: Glucose test system**
Panel: Clinical Chemistry 75
Product Code: NBW, System, Test, Blood Glucose, Over The Counter.
Classification: Class II

4. **Device Description:**
Our Blood Glucose Monitoring System consists of a Meter, Blood Glucose Test Strips, Code Key, Check key, Two Control Solutions, Lancing Device and lancets. The Rightest Meter, Blood Glucose Test Strips, Code Key and Check key are manufactured by BIONIME Corporation. **The Rightest Meter, when used with the Rightest Test Strips Blood Glucose Test Strips, quantitatively measures glucose in fresh capillary whole blood. The performance of the Rightest Blood Glucose Test Strips is verified by the Control Solution. The Check key verifies the status of Rightest meter.**

5. **Intended Use:**
The Rightest Blood Glucose Monitoring System is intended for in vitro diagnostic use (outside of body). It is indicated to used by professional healthcare personnel or people with diabetes at home to measure the glucose concentration for aiding diabetes management. The glucose concentration is measured with quantitative capillary whole blood from fingertip, palm and forearm by using Rightest Blood Glucose Monitoring System. This test device is not intended for testing neonate blood samples.
Special condition for use statement(s): Rightest system provides plasma equivalent results.

6. **Predicate Device Information:**

The Rightest Blood Glucose Monitoring System is substantially equivalent to the brand of Rightest Blood Glucose Monitoring System noted below.

Name: **Rightest Blood Glucose Monitoring System**
Device Company: **Bionime Corporation**
510(K) Number: **K042678 and K053635**

7. **Comparison to Predicate Devices:**

Similarities		
Item	**Device**	**Predicate**
	Rightest BGMS (Alternative Site Testing)	**Rightest BGMS**
Detection method	Amperometry	Amperometry
Enzyme	Glucose Oxidase (Aspergillus niger)	Glucose Oxidase (Aspergillus niger)
Mediator	Potassium ferricyanide	Potassium ferricyanide
Hematocrit Range	30 – 55%	30 – 55%
Temperature range	50 - 104° F 10 - 40° C	50 - 104° F 10 - 40° C
Humidity range	10 – 90%	10 – 90%
Warranty(meter)	3 years	3 years
Open use time (strip)	3 months	3 months
Electrode	Noble metal electrode	Noble metal electrode
Coding	Code key	Code key
Power	1.5V×2 battery (LR03)	1.5V×2 battery (LR03)
Test range	20 – 600 mg/dL	20 – 600 mg/dL

Differences		
Item	**Device(Alternative Site Testing)**	**Predicate**
	Rightest BGMS (AST)	**Rightest BGMS**
Sample Source	The glucose concentration is measured with quantitative capillary whole blood from the fingertip, palm and forearm by using Rightest Blood Glucose Monitoring System.	The glucose concentration is measured with quantitative capillary whole blood from the fingertip, palm and forearm by using Rightest Blood Glucose Monitoring System.
Description and Labelling	We mention the information about modification in user's	We mention the information in user's manual.

	manual. We also show a diagrammatic explanation about alternative test sites in user's manual.	
Test Time	8 seconds	15 seconds
Sample Volume	1.4 uL	2 uL
Memory capability	1, 7, 14, 30 day average and last 300 tests in the memory	3, 7, 14 day average and last 200 tests in the memory
Battery life	Running 1,000 test	Running 1,500 test
The unit of measurement data	Fix on mg/dL	Switch between mg/dL and mmol/L

8. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Verification and validation of test results were evaluated to establish the performance, functionality and reliability of The Rightest Blood Glucose Monitoring System.

The evaluation included with precision, linearity, interference, hematocrit and control solution.

9. **Discussion of Clinical Tests Performed:**

The clinical test was designed in Alternative site testing study as below

Test capillary blood by technician Study:

It shows similarly slope and intercept for difference position of capillary blood test by technician.

Fig 1 Linear regression from Rightest versus YSI 2300D

Technician	*Rightest **fingerstick** vs YSI-Plasma*	*Rightest **palmstick** vs YSI-Plasma*	*Rightest **armstick** vs YSI-Plasma*
Test range		*30 ~ 572*	
Test number	*176*	*176*	*174*
Slope	*0.99*	*1.01*	*0.99*
Intercept	*2.51*	*1.70*	*2.21*
r	*0.9901*	*0.9910*	*0.9882*

Test capillary blood by patient Study:

It shows similarly slope and intercept of difference positions of capillary blood test by Patient.

Fig 2 Linear regression from Rightest versus YSI 2300D

Patient	*Rightest **fingerstick** vs YSI-Plasma*	*Rightest **palmstick** vs YSI-Plasma*	*Rightest **armstick** vs YSI-Plasma*
Test range		*30 ~ 572*	
Test number	*176*	*175*	*174*

Slope	*1.03*	*1.02*	*1.02*
Intercept	*-0.25*	*1.19*	*-0.84*
r	*0.9911*	*0.9912*	*0.9906*

The "Alternative Site Test" clinical evaluation shows substantial equivalence to Rightest used in finger, palm and arm position. They all have similar slope and intercept of Rightest value versus YSI 2300D. So the result tells us Rightest blood glucose monitoring system is suitable to be used in finger, palm and arm.

10. <u>Conclusions:</u>

Results of clinical testing demonstrate that the performance of the Rightest Blood Glucose Monitoring System (Alternative Site Testing) testing capillary whole blood is substantial equivalence of Rightest Blood Glucose Monitoring System. The precision and accuracy of Rightest is suitable for its in monitoring the effectiveness of diabetes management at home and in clinical settings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Bionime Corporation
c/o Ms. Susan D. Goldstein-Falk
MDI Consultant, Inc.
55 Northern Blvd.
Suite 200
Great Neck, NY 11021

FEB 16 2007

Re: k062567
Trade/Device Name: Rightest Blood Glucose Monitoring System
Regulation Number: 21 CFR § 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: February 2, 2007
Received: February 5, 2007

Dear Ms. Goldstein-Falk:

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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_ **k062567**

Device Name: **Rightest Blood Glucose Monitoring System**

Indications For Use:

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Special conditions for use statement(s): Rightest System provides plasma equivalent results.

Prescription Use ___X____ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use ____X__ (21 CFR 807 Subpart C)

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

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

[signature]

[illegible] In Vitro Diagnostic Devices
[illegible] and Safety

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