Exhibit 1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K072054

1. Submitter's Identification:

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

Date Summary Prepared: September 10, 2007

2. Name of the Device: Rightest Blood Glucose Monitoring System, Model GM310

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 be 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 (Sample volume/Reaction Time) is substantially equivalent to the brand of Rightest Blood Glucose Monitoring System (Alternative Site Testing) noted below.

Name:	Rightest Blood Glucose Monitoring System
Device Company:	Bionime Corporation
510(K) Number:	K042678, K053635 and K062567

7. Comparison to Predicate Devices:

Similarities		
Item	Subject Device	Predicate Device(s)
	Rightest BGMS (Sample volume/Reaction Time)	Rightest BGMS (Alternative Site Testing)
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)

Differences		
Item	Subject Device (Sample Volume/Reaction Time)	Predicate Device(s)
	Rightest BGMS	Rightest BGMS(AST)

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 manual. We also show a diagrammatic explanation about alternative test sites in user's manual.	We mention the information about modification in user's manual. We also show a diagrammatic explanation about alternative test sites in user's manual.
Test range	20 – 600 mg/dL	20 – 600 mg/dL
Test Time	5 seconds	8 seconds
Sample Volume	0.5 uL	1.4 uL
Memory capability	1, 7, 14, 30 day average and last 300 tests in the memory	1, 7, 14, 30 day average and last 300 tests in the memory
Battery life	Running 1,000 test	Running 1,000 test
The unit of measurement data	Fix on mg/dL	Fix on mg/dL
Interference	Uric acid > 9.0 mg/dL Cholesterol > 500 mg/dL	Uric acid > 9.0 mg/dL L-Doga > 1.5 ml/dL Methyldopa > 1.5 mg/dL Cholesterol > 250 mg/dL

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 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 patient Study:
It shows similarly slope and intercept for difference position of capillary blood test by patient.

Fig 1 Linear regression from Rightest versus Olympus AU640

Technician	*Rightest fingerstick vs Olympus-Plasma*	*Rightest palmstick vs Olympus-Plasma*	*Rightest armstick vs Olympus-Plasma*
Test range (mg/dL)	*32~590*	*31~564*	*34~582*
Test number	*120*	*120*	*120*
Slope	*0.99*	*0.98*	*0.95*
Intercept	*0.67*	*3.17*	*5.26*
r	*0.994*	*0.995*	*0.985*

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 Olympus AU640. So the result tells us Rightest blood glucose monitoring system (Sample volume/Reaction Time) is suitable to be used in finger, palm and arm.

10. Conclusions:

Results of clinical testing demonstrate that the performance of the Rightest Blood Glucose Monitoring System (Sample volume/Reaction Time) testing capillary whole blood is substantial equivalence of Rightest Blood Glucose Monitoring System (AST). 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

FEB 28 2008

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

Re: k072054
Trade/Device Name: Rightest Blood Glucose Monitoring System Model GM310
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system.
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: January 23, 2008
Received: January 24, 2008

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): K072054

Device Name: **Rightest Blood Glucose Monitoring System, Model GM310**

Indications For Use:

The Rightest Blood Glucose Monitoring System is intended for in vitro diagnostic use (outside of body). It is indicated to be used by professional healthcare personnel or diabetics at home to measure the glucose concentration for aiding diabetes management. The glucose concentration is measured with quantitative capillary whole blood from the fingertip, palm, and forearm by using Rightest Blood Glucose Monitoring System. This device is not intended for testing neonate blood samples.

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)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K072054