JAN - 3 2005

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: K042678

1. **Submitter's Identification:**

BIONIME CORPORATION
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: September 28, 2004.

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 includes Meter, Blood Glucose Test Strips, Code Key, Check key, One Control Solution, Lancing Device and lancets.
Rightest meter, Blood Glucose Test Strips, Code Key and Check key are manufactured by BIONIME Corporation. The Rightest Meter, when used with the Rightest Blood Glucose Test Strips, quantitatively measures glucose in fresh capillary whole blood.

The performance of the Rightest Blood Glucose Test Strips is verified by 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 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 by using Rightest Blood Glucose Monitoring System.

This 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 ONE TOUCH Ultra noted below.

Name: ONE TOUCH® Ultra® Blood Glucose Monitoring System
Device Company: Lifescan, Inc.
510(K) Number: K024194

7. **Comparison to the Predicate Device:**

Similarities		
Item	**Device**	**Predicate**
	Rightest	**ONE TOUCH® Ultra®**
Detection method	Amperometry	Amperometry
Enzyme	Glucose Oxidase (Aspergillus niger)	Glucose Oxidase (Aspergillus niger)
Mediator	Potassium ferricyanide	Potassium ferricyanide
Test range	20 – 600 mg/dL	20 – 600 mg/ dL
Hematocrit Range	30 – 55%	30 – 55%
Temperature range	50 - 104° F 10 – 40° C	43 - 111° F 6 - 44° C
Humidity range	10 – 90%	10 - 90%
Warranty(meter)	3 years	3 years
Open use time (strip)	3 months	3 months

Differences		
Item	**Device**	**Predicate**
	Rightest	**ONE TOUCH® ULTRA®**
Electrode	Noble metal electrode	Carbon electrode
Coding	Code key	Button (C1 – C49)
Test Time	15 seconds	5 seconds
Sample Volume	2 uL	1 uL
Memory capability	3, 7, 14 day average and last 200 tests in the memory	14-day average and last 150 tests in the memory
Power	1.5V×2 battery (LR03)	3V Li battery (CR2032)
Battery life	Running 1,500 test	Running 1,000 test
Size: LxWxH	85.0x58.0x22.5	79x57x21

(mm)		
Weight	85g (with battery)	42g (with battery)

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. Testing included precision testing, linearity testing, sensitivity testing, interference testing, stability testing and electrical/EMC testing.

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

Clinical testing included a consumer study and point of care study as outlined below:

Consumer Study (field test):

Linear regression was established between lay user (Y axial) and technician (X axial).

Blood type	Capillary whole blood
Patient number	128
Testing range	56.0 ~ 556 mg/dL
Slope	1.0066
Intercept	-0.576
R	0.9959

Point Of Care Study:

A direct correlation between *the* YSI 2300D *glucose analyzer* (X axial) and *Rightest Blood Glucose Monitoring System* (Y axial) were confirmed in the 309 blood samples. Results obtained by 3 positions in the same general hospital presented the following regression:

Blood type	Capillary Whole Blood	Venous Whole Blood	Venous Plasma
Patient number		309	
Testing range		68.0 ~ 565 mg/dL	
Slope	1.0025	1.1806	1.819
Intercept	4.509	-1.362	2.280
R	0.9886	0.9873	0.9980

10. Conclusions:

Results of evaluation and clinical testing demonstrate that the performance of the Rightest Blood Glucose Monitoring System testing capillary whole blood is substantially equivalent to the predicate device, ONE TOUCH® Ultra® Blood Glucose Monitoring System. The precision and accuracy of Rightest is suitable for its use in monitoring the effectiveness of diabetes management at home and in clinical settings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN - 3 2005

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

Re: k042678
Trade/Device Name: Rightest Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: December 17, 2004
Received: December 20, 2004

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)276-0484. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Patricia Bernhardt for C. Rooks

Cornelia B. Rooks, MA
Acting 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):

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

Indications For Use:

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This test device is not intended for testing neonate blood samples.

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

Prescription Use __x_____ AND/OR Over-The-Counter Use __x__
(Part 21 CFR 801 Subpart D) (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)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K042678