

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE**

A. 510(k) Number:

k113007

B. Purpose for Submission:

New 510(k) for diabetes data management software accessory for use with compatible cleared GM550 and GM250 Blood Glucose Monitoring Systems (k092052).

C. Manufacturer and Instrument Name:

Bionime Corporation. Bionime Diabetes Management System Software

D. Type of Test or Tests Performed:

Diabetes data management system

E. System Descriptions:

1. Device Description:

The Bionime Diabetes Management System allows the transfer of blood glucose readings from a compatible Bionime Rightest Glucose Meter to a PC via USB cable.

The Data analysis features enable the user(s) to view and analyze blood glucose readings from different meal times or time periods up to 90 days. Other features including data tables, trend charts, pie charts, and printed reports are available for viewing and analyzing these readings within the different time slots.

The system is comprised of two components. The first component is an Installation CD with setup files for Bionime GP200 Diabetes Assistant Software and Rightest PC Link Adapter Driver. The second component is GP550 PC Link Adapter.

2. Principles of Operation:

The Bionime Diabetes Management System is an accessory to compatible Rightest meters, which use specific test principles.

Operating System requirements for the Bionime Diabetes Management System are: Windows XP Professional, Windows Vista Professional or Windows 7 Professional. The system requirements are as follows: (1) Microsoft Windows personal computer, (2) CPU: 550 MHz Intel Pentium 3 or above, (3) DRAM: 512 or above, (4) HD: 600 MB or more, (5) Internet Explorer 7.0 or above, (6) USB 2.0 or above, (7) LCD screen with resolution of 1024x768 or above, (8) CD-ROM drive and (9) a printer (Optional).

3. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes or No .

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission:

Yes or No .

4. Specimen Identification:

Specimen identification is based on time and date of testing.

5. Specimen Sampling and Handling:

Data transmission from glucose meters using capillary whole blood samples

6. Calibration:

Glucose meter specific. See statement below under section J.

7. Quality Control:

Glucose meter specific. See statement below under section J.

8. Software:

FDA has reviewed applicant's Hazard Analysis and Software Documentation:

Yes or No .

F. Regulatory Information:

Device Name	Product Code	Classification	Regulation	Panel
Glucose Test System	NBW: Blood Glucose Test System, Over-the-Counter	Class II	21 CFR § 862.1345	Clinical Chemistry (75)
Calculator/Data Processing Module for Clinical Use	JQP: Calculator/Data Processing Module for Clinical Use	Class I	21 CFR § 862.2100	Clinical Chemistry (75)

G. Intended Use:

1. Indication(s) for Use:

The Bionime Diabetes Management System is an over-the-counter software system for use by Health Care Professionals and Patients with diabetes as an aid for managing diabetes. User(s) can transfer blood glucose readings from Rightest Glucose meter(s) to a personal computer for the purpose of viewing, analyzing

and printing the glucose readings, as well as to backup and to recover users' profile and data.

The Bionime Diabetes Management System is not intended to provide treatment decisions, nor should it substitute professional opinion. All medical diagnoses and treatment plans should be performed by a licensed healthcare professional.

2. Special Conditions for Use Statement(s):
For Over-the-Counter (OTC) use.

H. Substantial Equivalence Information:

Predicate device name	Predicate 510(k) number
Glucofacts Deluxe Diabetes Management Software	k091820

Comparison with predicate:

Similarities and Differences		
Item	Candidate Device Bionime Diabetes Management System	Predicate Device (k091820)
Intended Use	The Bionime Diabetes Management System is an over-the-counter software system for use by Health Care Professionals and Patients with diabetes as an aid for managing diabetes.	<u>Same</u>
Meter Compatibility	For use with supported glucose meters	Same
Download blood glucose meter readings via USB interface cable	Yes	Same
Set-up multiple patient databases	Yes	Same
Create trending graphs and reports	Yes	Same

I. Special Control/Guidance Document Referenced (if applicable):

- EN 61326-1: 2006, Electrical equipment for measurement, control and laboratory use – EMC requirements Part 1: General requirements for safety Collateral standard: Electromagnetic compatibility Requirements and tests- Edition 2.1; Edition 2:2001 consolidated with amendment 1:2004
- EN 61326-2-6: 2006, Electrical equipment for measurement, control and laboratory use – EMC requirements Part 2-6: Particular requirements.

- EN 60601-1-2:2001/A1: 2006, Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility - Requirements and tests
- ISO 14971: 2007, Medical Devices- Application of risk management to medical devices.

J. Performance Characteristics:

1. Analytical Performance:
The performance characteristics listed below as applicable, were presented in the specific glucose meter clearance under k092052.
 - a. *Accuracy:*
See above statement under section J(1).
 - b. *Precision/Reproducibility:*
See above statement under section J(1).
 - c. *Linearity:*
See above statement under section J(1).
 - d. *Carryover:*
See above statement under section J(1).
 - e. *Interfering Substances:*
See above statement under section J(1).
2. Other Supportive Instrument Performance Data Not Covered Above:
 - a) A usability study was performed with 29 lay-user participants with varying demographics (age, sex, and education level) were included in a usability study. Those study participants also completed a questionnaire in response to whether the data transmission feature is easy to use. The sponsor concluded that the user's responses indicated that data transmission function was easy to operate by following the instructions provided with the system.
 - b) The following documentation related to the software was reviewed and found to be acceptable: level of concern, software description, device hazard analysis, software requirements specifications, software design specification, software development environment description, and verification and validation testing.
 - c) The sponsor provided the results of a Flesch-Kincaid readability study which indicated a Grade Level Score of 8th grade or below for the Bionime Diabetes Management System User Manual.

- d) The sponsors provided the appropriate documentation certifying that electromagnetic testing (EMC) had been performed and the GP550 PC-Link Adaptor were found compliant (EN 61326, EN 61326-2-6).

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.