

510(k) Summary

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

510(k) Number: K103544

Prepared: December 5, 2011

Submitter: AgaMatrix, Inc.

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Contact: William H. McGrail
Executive Director, Regulatory & Clinical Affairs

Device Name: Trade/Proprietary Name: iBGStar Blood Glucose Monitoring System
Common Name: Glucose Test System

Product Name: iBGStar Diabetes Manager Application
Common Name: Diabetes Management Software

Device Classification:

Product Code	Classification	Regulation Section	Panel
CGA – glucose Oxidase	Class II	21 CFR 862.1345	75, Clinical Chemistry
NBW – system, test, blood glucose, over the counter	Class II	21 CFR 862.1345	75, Clinical Chemistry
JJX- Quality Control Material	Class I	21 CFR 862.1660	75, Clinical Chemistry
JQP - Calculator/data processing module for clinical use.	Class I	21 CFR 862.2100	75, Clinical Chemistry

Predicate Device: 1) Jazz Blood Glucose Monitoring System, 510(k) # k071393
2) WaveSense Diabetes Manager, 510(k) # 5101597

Device Description: The iBGStar Blood Glucose Monitoring System consists of:

- iBGStar Blood Glucose Meter
- BGStar Test Strips
- BGStar Control Solution



Intended Use:

The iBGStar™ Blood Glucose Monitoring System is intended for the quantitative measurement of blood glucose levels in fresh capillary whole blood samples drawn from the fingertip, palms (at the base of the thumb), or forearms. It is intended to be used by a single patient and should not be used for testing multiple patients. The iBGStar™ Blood Glucose Monitoring System is intended for self testing outside the body (In vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The iBGStar Blood Glucose Monitoring System is not for the diagnosis of, or screening for diabetes, and is not intended for use with neonates.

The iBGStar Diabetes Manager Application is intended for use in the home with the capability of sending glucose readings through email to an individual's healthcare professional in the review, analysis and evaluation of glucose test results to support an effective diabetes management program. It is an optional data management software accessory for use with the iBGStar Blood Glucose Monitoring System.

Technological Characteristics:

There were no changes to the fundamental scientific technology.

Comparison to Predicate:

1) The iBGStar BGMS has the following similarities to the predicate device:

Item	Jazz BGMS	iBGStar BGMS
Indications for Use	Blood glucose monitoring	Same
Intended Use	Home Use	Same
Calibration	No coding required	Same
Test Principle/Enzyme	Glucose Oxidase	Same
System Characteristics	Operating Temp, Test Time, Test Range, Sample Size, Test strips	Same

The iBGStar BGMS has the following differences from the predicate device:

Item	Jazz BGMS	iBGStar BGMS
Backlight	Yes	No
Number of results stored	1865	300
Power Source	Two (2) CR-2032, 3 volt,	Polymer lithium-ion
Size	L-84 mm, W-46 mm, H-19.5	L-56 mm, W-24 mm, H-10
Weight	48g	8.5g



2) The iBGStar Diabetes Manager app has the following similarities to the predicate device:

Item	WaveSense Diabetes Manager app (predicate device)	iBGStar Diabetes Manager app
Indications for Use	Download glucose readings to a data management system to aid in the effective management of diabetes.	Same
Intended Use	Home Use	Same
Management Tools	Logbook and Trend Charts	Same

The iBGStar Diabetes Manager app has the following differences from the predicate device:

Item	WaveSense Diabetes	iBGStar Diabetes Manager app
Upload To	PC (computer)	Device compatible with the iPhone Operating System platform
Transfer of Glucose Readings	Cable Download	The iBGStar meter directly connects to idevice

Assessment of Performance:

An evaluation of the iBGStar BGMS and iBGStar Diabetes Manager Application were studied in house and in a clinical setting by person with diabetes. The studies demonstrated the ease of operating the iBGStar BGMS and iBGStar Diabetes Manager Application as intended.

Conclusion:

The results of clinical evaluations of the iBGStar BGMS and the iBGStar Diabetes Manager app demonstrate the meter and application are equivalent in performance to the predicate devices and suitable for its intended use.



AgaMatrix, Inc.
c/o William McGrail
7C Raymond Ave
Salem, NH 03079

JAN 11 2012

Re: k103544
Trade Name: iBGStar Blood Glucose Monitoring System, iBGStar Diabetes
Manager Application, BGStar Control Solutions
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: CGA, JQP, NBW, JJX
Dated: November 23, 2011
Received: November 25, 2011

Dear Mr. McGrail:

This letter corrects our letter of December 7, 2011.

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 H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure



AgaMatrix, Inc.
7C Raymond Ave
Salem, NH 03079 USA

Indications for Use

510(k) Number (if known): K103544

Device Name: iBGStar Blood Glucose Monitoring System, iBGStar Diabetes Manager Application

Indications for Use:

The iBGStar™ Blood Glucose Monitoring

The iBGStar™ Blood Glucose Monitoring System is Intended for the quantitative measurement of blood glucose levels in fresh capillary whole blood samples drawn from the fingertip, palms (at the base of the thumb), or forearms. It is intended to be used by a single patient and should not be used for testing multiple patients. The iBGStar™ Blood Glucose Monitoring System is intended for self testing outside the body (*In vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The iBGStar Blood Glucose Monitoring System is not for the diagnosis of, or screening for diabetes, and is not intended for use with neonates.

BGStar™ Test Strips

BGStar™ Test Strips are for use with the iBGStar™ Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip, palms (at the base of the thumb), or forearms. Palm and forearm testing (Alternative Site Testing) should be done only during steady-state times (when glucose is not changing rapidly).

BGStar Control Solutions

BGStar Control Solutions are for use with the iBGStar™ Blood Glucose Meter and BGStar Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

The iBGStar Diabetes Manager Application – Home Use

The iBGStar Diabetes Manager Application is intended for use in the home with the capability of sending glucose readings through email to an individual's healthcare professional in the review, analysis and evaluation of glucose test results to support an effective diabetes management program. It is an optional data management software accessory for use with the iBGStar Blood Glucose Monitoring System.

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

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

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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