BIONOSTICS
Quality Solutions

K082395

SEP 18 2008

510(k) Summary[2]

(a) (1) Submitter's name, address

Bionostics, Inc.
7 Jackson Road
Devens, MA 01434

Contact Person

Kathleen Storro
Sr. Dir. QA/RA
(978) 772-7070 x 220

Date of preparation of this summary: 18 August 2008

(2) Device trade or proprietary name: Glucose Meter-Check™ Control Solution
For Bayer Ascensia Blood Glucose Test Systems

Device common or usual name or classification name:

75 JJX, single (specified) analyte controls (assayed and unassayed)

	CLASSIFICATION		
PRODUCT NOMENCLATURE	**NUMBER**	**CLASS**	**PANEL**
SINGLE ANALYTE CONTROL SOLUTION	862.1660	I	75 CLINICAL CHEMISTRY

I. Substantial Equivalence

Glucose Meter-Check™ Control Solution for Bayer Ascensia Blood Glucose Test Systems is substantially equivalent in function, safety and efficacy to currently marketed devices for the same intended use:

Comparison of Glucose Meter-Check™ Control Solution to predicate devices for substantial equivalency

Product	Glucose Meter-Check Solution	Ascensia Breeze 2	Ascensia Contour	Ascensia Elite	Ascensia DEX 2	SMS Glucose Control
510(k), Date		K062347 11-21-06	K023657 05-11-04	K043311 12-22-04	K023584 11-20-02	K070506 04-18-07
Net Fill	4 mL	2.5 mL	2.5 mL	2.5 mL	2.5 mL	3.6 mL
Color	red	red	red	red	red	Red
Analyte	glucose	glucose	glucose	glucose	glucose	Glucose
Glucose (% w/v)	0.1%	0.10%	0.12%	0.10%	0.15%	0.12%
Container	plastic vial	plastic vial	plastic vial	plastic vial	plastic vial	plastic vial
Matrix	aqueous	aqueous	aqueous	aqueous	aqueous	aqueous
Level	normal	normal	normal	normal	normal	normal
Mid Assigned Value* (mg/dL)	86	108	122	88	140	110

* Mid Assigned Value is the mean of assigned values for each meter (Ascensia Contour for Glucose Meter-Check and SMS Glucose Control)

[2] This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

II. **Description of the new device**

Glucose Meter-Check™ Control Solution is a single-level, viscosity-adjusted, aqueous liquid glucose control solution. **Glucose Meter-Check™ Control Solution** is intended for use to verify the performance of Bayer Ascensia brand blood glucose test systems listed in the package insert at glucose levels within the normal fasting blood glucose range for non-diabetic persons. The product is packaged in plastic bottles with dropper tips for application of the solution to test strips. The control has a red color to help users see the solution while dispensing onto a test strip.

Glucose Meter-Check™ Control Solution is a non-hazardous aqueous solution containing no human or animal-derived materials.

(a) (1) Intended use of the device

Glucose Meter-Check™ Control Solution is intended for in vitro diagnostic use to assess the performance of the Bayer Ascensia blood glucose test systems: Breeze 2, Contour, Elite and DEX 2 by healthcare professionals and in the home by people with diabetes mellitus.

(a) (2) Technological characteristics of the device.

This material consists of viscosity-adjusted, aqueous glucose control solution prepared with a single concentration of D-glucose and has been optimized to simulate the response of whole blood on the Bayer Ascensia blood glucose test systems. The solution contains no hazardous, human or animal derived components.

(b) (1) Summary of non-clinical tests submitted with the premarket notification for the device.

Tests were conducted to verify specific performance requirements:

a) Closed bottle stability
b) Stability after opening
c) Test mean response and precision data

(b) (2) Summary of clinical tests submitted with the premarket notification for the device.

N/A

(b) (3) Conclusions drawn from the clinical and non-clinical trials.

Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Bionostics, Inc.
c/o Ms Kathleen Storro
7 Jackson RD.
Devens, MA 01434

SEP 18 2008

Re: k082395

Trade/Device Name: Glucose Meter-Check Control Solution for Bayer Ascensia Blood Glucose Test Systems
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I, Reserved
Product Codes: JJX
Dated: August 18, 2008
Received: August 20, 2008

Dear Ms. Storro:

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

Indication for Use

510(k) Number (if known): K082395

Device Name: Glucose Meter-Check™ Control Solution for Bayer Ascensia Blood Glucose Test Systems

Indication For Use: Glucose Meter-Check™ Control Solution is intended to assess the performance of the following Bayer blood glucose test systems:

- Bayer Ascensia Breeze® 2
- Bayer Ascensia Contour®
- Bayer Ascensia Elite®
- Bayer Ascensia DEX® 2

The Meter-Check Glucose Control Solution is intended for use by healthcare professional and people with diabetes mellitus at home.

For *In Vitro* Diagnostics Use

Prescription Use _____	And/Or	Over the Counter Use ___✓___
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Ann Chapie

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

510(k) K082395