K091914

BIONOSTICS
Quality Solutions

510(k) Summary[1]

NOV - 6 2009

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

Bionostics, Inc.
7 Jackson Road
Devens, MA 01434

Contact Person

Minna Rannikko
Director, R&D
(978) 772-7070 x 236

Date of preparation of this summary: 5 October 2009

(2) **Device trade or proprietary name:** OMNIS Health Embrace Glucose Control Solution

Device common or usual name or classification name:

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

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

I. **Substantial Equivalence**

OMNIS Health Embrace Glucose Control Solution is substantially equivalent in function, safety and efficacy to currently marketed devices for the same intended use:

Comparison of OMNIS Health Embrace Glucose Control Solution to predicate devices for substantial equivalency

Product	OMNIS Health L1 Low Solution	Embrace L1 Low Control	OMNIS Health L2 High Solution	Embrace L2 High Control
510(k)		K090043		K090043
Net Fill	4 mL	2.5 mL	4 mL	2.5 mL
Color	red	red	red	red
Analyte	glucose	glucose	glucose	glucose
Glucose (% w/v)	0.08%	0.06%	0.15%	0.15%
Container	6 mL plastic vial	3 mL plastic vial	6 mL plastic vial	3 mL plastic vial
Matrix	aqueous	aqueous	aqueous	aqueous
Level	L1 (low)	L1 (low)	L2 (high)	L2 (high)
Mid Assigned Value* (mg/dL)	114	114	229	229

* Mid Assigned Value is the mid-point of assigned ranges on OMNIS Health glucose test strips.

[1] 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**

OMNIS Health Embrace Glucose Control Solution is a two-level, viscosity-adjusted, aqueous liquid glucose control solution. **OMNIS Health Embrace Glucose Control Solution** is intended for use to verify the performance of OMNIS Health Embrace blood glucose test systems at glucose levels within the normal fasting blood glucose range for non-diabetic persons, and at elevated ranges consistent with hyperglycemia. 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.

OMNIS Health Embrace Glucose Control Solution is a non-hazardous aqueous solution containing no human or animal-derived materials.

(a) (1) Intended use of the device

OMNIS Health Embrace Glucose Control Solution is intended for in vitro diagnostic use to assess the performance of the OMNIS Health Embrace blood glucose test systems 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 at two concentrations of D-glucose and has been optimized to simulate the response of whole blood on OMNIS Health Embrace 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 (Shelf-life)
b) Stability after opening (Use-life)
c) Transport Stability
d) Preservative Efficacy
e) 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

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Bionostics, Inc.
c/o Ms. Minna Rannikko
Director, Research and Development
7 Jackson Road
Devens, MA 01434

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Re: k091914
Trade/Device Name: OMNIS Health Embrace Glucose Control Solution
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I (reserved)
Product Code: JJX
Dated: September 23, 2009
Received: September 24, 2009

Dear Ms. Rannikko:

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 C. Harper, Ph.D.
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: **OMNIS Health Embrace Glucose Control Solution**

Indication For Use:

OMNIS Health Embrace Glucose Control Solution is intended to assess the performance of OMNIS Health Embrace Blood Glucose test systems. OMNIS Health Embrace Glucose Control Solution is intended for use by healthcare professionals and people with diabetes mellitus at home.

For *In Vitro* Diagnostic Use

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use ✓ (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)

Carol Benson

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

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