K133197

JAN 17 2014

510(k) Summary

Date of Preparation: January 10, 2014

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter:
Fujirebio Diagnostics, Inc.
940 Crossroads Blvd
Seguin, TX 78155
Phone: (830) 372-1391 ex. 210
Fax: (830) 372-4130
Establishment Registration Number: 1643621

Contact Person: Kent Pruett

Device Name: FDI Level I and Level II Glucose Controls for the Embrace No Code

Common Name: Single Analyte Control Solution, All Types (Assayed and Unassayed)

Classification Name: Quality Control Material (assayed and unassayed).

Classification: Class I, Reserved per 21 CFR 862.1660

Product Code: JJX

Panel: 75 (Chemistry)

Predicate Device:

Name:	Omnis Embrace Glucose Control Solutions
Manufacturer:	Bionostics
510(k) No.:	k091914

Device Description: The FDI Glucose Controls for the Embrace No Code consist of a viscosity-adjusted, aqueous liquid control solution containing known quantities of glucose. The product is packaged in plastic dropper tipped bottles for easy application of the control and a red coloration to aid the user to visually confirm application. The product is non-hazardous and contains no human or animal derived materials.

Intended Use: The FDI Glucose Controls are intended for use with Omnis Embrace No Code blood glucose meter and test strips. The controls are used to check that the meter and test strips are working together properly.

Comparison to Predicate Devices:

Characteristic/ Aspect		Predicate Device	New Product
Name		Omnis Embrace Glucose Control Solutions	FDI Level I and Level II Glucose Controls for the Embrace No Code
510(k), Date		k091914 11/06/2009	
Number of Levels		2	Same
Analyte		Glucose	Same
Glucose (% w/v)	I	0.08%[1]	0.07%
	II	0.15%[1]	Same
Target Range (mg/dL)	I	88 – 136[2]	Same[3]
	II	174 - 269[2]	179 – 275[3]
Container		Plastic bottle with dropper-tip	Same
Fill Volume		4.0 mL	3.6 mL
Color		Red	Same
Matrix		Viscosity-adjusted, aqueous glucose control solution of D-glucose and other non-reactive ingredients	Buffered aqueous solution of D-Glucose, a viscosity modifier, preservatives, and other non-reactive ingredients
Indications for Use		To validate the performance of the blood glucose monitoring system.	To check that the meter and test strips are working together properly.
Target Population		Professional and home use	Same

[1]Based data presented in k091914 Decision Summary
[2]Derived from the control ranges assigned by the manufacturer
[3]Based on a +/- 5% glucose concentration variability lot-to-lot and ± 20% range

Performance Studies: Tests were performed to verify specific performance characteristics:

Real Time Stability: Samples were periodically removed and tested in triplicate on a commercially available clinical chemistry analyzer. The study supports a shelf life of 24 months when stored at 15–30°C.

Open Vial Stability: A number of test and control vials was evaluated for 13 weeks. Each day all test group vials were opened, allowed to stand for ten minutes, then closed and stored at room temperature. Each week one test group vial and one control group vial was assayed in triplicate using the ACE Glucose assay. The Control vial was opened on the date of performing the assay and then discarded after testing was complete. The study supports the claimed open vial stability of 90 days when stored at 15 - 30°C.

Test Precision: Studies performed per CLSI Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition. CLSI document EP5-A2; 2004. No precision claims will be made for this product.

Value Assignment: The control solutions are analyzed using a single Embrace No Code monitor using three different lots of test strips, 10 replicates per strip lot, over three days. Range of acceptable values for each level is determined by calculating ± 20% of each control lot's calculated mean for three lots of strips. Acceptable ranges are based on predetermined acceptance criteria for glucose recovery for each lot. The glucose control value ranges are lot dependent; therefore the range for each lot is printed on the control solution vial label.

Traceability: Each control is traceable to a 70 mg/dL (Low) and a 150 mg/dL (High) in-house Standard traceable to the NIST Standard Reference Material 917. The in-house Standards are produced using SRM917.

Conclusion: Comparison of the performance characteristics, formulation and intended use support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 17, 2014

FUJIREBIO DIAGNOSTICS, INC.
KENT PRUETT
DIRECTOR OF QUALITY/REGULATORY AFFAIRS
940 CROSSROADS BLVD
SEGUIN TX 78155

Re: K133197
Trade/Device Name: FDI Level I and Level II Glucose Controls For The Embrace No Code
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJX
Dated: October 29, 2013
Received: November 5, 2013

Dear Mr. Pruett:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133197

Device Name
FDI Level I and Level II Glucose Controls for the Embrace No Code

Indications for Use *(Describe)*

The FDI Glucose Controls are intended for use with Embrace No Code blood glucose meter and test strips. The controls are used to check that the meter and test strips are working together properly.

The FDI Glucose Controls for the Embrace No Code are intended for use by healthcare professionals and people with diabetes mellitus at home.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [X] Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Stayce Beck

PSC Publishing Services (301) 443-6740 EF