BIONOSTICS
Quality Solutions

K112352

DEC 23 2011

510(k) Summary[1]

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

Bionostics, Inc.
7 Jackson Road
Devens, MA 01434

Contact Person

Randy Byrd
VP, Chief Technical Officer
(978) 772-7070 x 272

Date of preparation of this summary: 12 August 2011

(2) Device trade or proprietary name: Glucose Meter-Check Control for NIPRO TRUEresult

Device common or usual name or classification name:

JJX Single (Specified) Analyte Control, All Types, Assayed and Unassayed

REGULATION MEDICAL SPECIALTY	REGULATION NUMBER	CLASS	REGULATION DESCRIPTION
Chemistry	862.1660	II	Glucose Control

I, reserved

I. Substantial Equivalence

Glucose Meter-Check Control Solution for NIPRO TRUEresult substantially equivalent in function, safety and efficacy to currently marketed devices for the same intended use as shown in the following tables:

Characteristic	Predicate Device	Modified Device
Name:	TRUEtest Control Solution *(for use with TRUEresult BGM)*	Glucose Meter-Check Control Solution for NIPRO TRUEresult
510(k), Date:	K080641, Aug 19, 2008	
Number of levels:	2, representing hypoglycemic, and typical fasting glucose levels	2, representing hypoglycemic, and typical fasting glucose levels
Analytes:	glucose	glucose
Container:	6 mL LDPE vial with dispensing tip and cap	6 mL LDPE vial with dispensing tip and cap
Fill volume:	4 mL	4 mL
Color:	Red	red
Matrix:	Buffered, aqueous solution of D-Glucose, viscosity modifier, preservatives and other, non-reactive ingredients.	Buffered, aqueous solution of D-Glucose, viscosity modifier, preservatives and other, non-reactive ingredients.
Brands:	TRUEtest	Glucose Meter-Check

II. **Description of the new device**

Glucose Meter-Check Control Solution for NIPRO TRUEresult is a buffered aqueous solution with glucose containing no ingredients of biological origin, or in concentrations qualifying as a controlled product under the Controlled Products Regulation. The Glucose Meter-Check Control Solution is formulated for optimal performance on NIPRO TRUEresult glucose meters. The product is provided in 2 levels, 1 representing hypoglycemia (low blood glucose) and 2, representing typical fasting blood glucose levels in non-diabetic persons.

(a) (1) Intended use of the device

Glucose Meter-Check Control Solution for NIPRO TRUEresult is intended for use to verify the performance and correct operation of the NIPRO TRUEresult Glucose Test Systems. Glucose Meter-Check Control Solution for NIPRO TRUEresult is intended for use by healthcare professionals and people with diabetes mellitus at home.

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

This material consists of viscosity-adjusted, aqueous glucose control solution prepared with a concentration of D-glucose to provide recovery on the test systems in the ranges typically considered hypoglycemic, and normal, fasting glucose for a non-diabetic person. This solution has been optimized to simulate the response of whole blood on the blood glucose test systems manufactured by NIPRO. 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) Test response

(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
Silver Spring, MD 20993

Bionostics, Inc.
Randy Byrd, Chief Technical Officer
7 Jackson Road
Devens, MA 01434

DEC 23 2011

Re: k112352

Trade/Device Name: Glucose Meter-Check Control Solutions level 1&2 for NIPRO TRUEresult Glucose Monitoring System
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I, reserved
Product Code: JJX
Dated: November 7, 2011
Received: December 8, 2011

Dear Mr. Byrd:

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 class II (Special Controls), 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). 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 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K112352

Device Name: Glucose Meter-Check® Control Solution for NIPRO TRUEresult®

Indications for Use: Glucose Meter-Check Control Solution for NIPRO TRUEresult is intended for use to verify the performance and correct operation of the NIPRO TRUEresult Glucose Test Systems. Glucose Meter-Check Control Solution for NIPRO TRUEresult is intended for use by healthcare professionals and people with diabetes mellitus at home.

For *In Vitro* Diagnostic Use

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

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

Concurrent of CDRH, Office of Device Evaluation (OIVD)

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

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