BIONOSTICS
Quality Solutions

K081478

OCT 0 6 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: 23 May 2008

(2) Device trade or proprietary name: RNA Medical Glucose and β-Ketone Calibration Verification Controls

Device common or usual name or classification name:

JJY, Multi-Analyte Controls, all Kinds (assayed)

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

I. Substantial Equivalence

RNA Medical Glucose and β-Ketone Calibration Verification Controls is substantially equivalent in function, safety and efficacy to currently marketed devices for the same intended use:

Comparison of RNA Medical Glucose and β-Ketone Calibration Verification Controls to predicate devices for substantial equivalency

Characteristic	Predicate Devices		Modified Device
Name:	RNA GL4 Glucose Calibration Verification Control	Precision Control Solutions	RNA Medical Glucose and β-Ketone Calibration Verification Controls
510(k), Date:	K021624, July 12, 2002	K983504, July 9, 1999	
Number of levels:	5* *7 vials per kit, only 5 levels for use on specific devices	3	5
Analytes:	Glucose	Glucose, Ketone	Glucose, Ketone
Container:	plastic bottle	plastic bottle	plastic bottle
Fill volume:	4 mL	3 mL	4 mL
Color:	Red	Clear	Red
Matrix:	Buffered aqueous solution of D-Glucose, viscosity modifier, dye, preservative and other non-reactive ingredients.	Buffered aqueous solution of D-Glucose, Beta-hydroxybutyrate and other non-reactive ingredients.	Buffered aqueous solution of D-Glucose, β-hydroxybutyrate, viscosity modifier, dye, preservative and other non-reactive ingredients.

[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

RNA Medical Glucose and β-Ketone Calibration Verification Controls is a five-level, viscosity-adjusted, aqueous liquid glucose and β-ketone control linearity set optimized for use with the Abbott Diabetes Care Precision Xceed Pro™ Blood Glucose and β-Ketone Monitoring System using Precision Xceed Pro Blood Glucose Test Strips and Precision Xceed Pro Blood β-Ketone Test Strips. **RNA Medical Glucose and β-Ketone Calibration Verification Controls** provides a convenient method of performing periodic QC checks for laboratories selecting to measure liquid QC material as part of their quality assurance program. 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.

RNA Medical Glucose and β-Ketone Calibration Verification Controls contains glucose and ketone values at the lower and upper limits of reportable range as well as three points within the range and therefore, may be used to assess the linearity and calibration, or verify performance of the blood glucose and blood ketone systems listed on the package insert.

Target midpoint values for Precision Xceed Pro Blood Glucose Test Strips and Precision Xceed Pro Blood β-Ketone Test Strips[3]

Analyte	Strip Type	Units	Level 1	Level 2	Level 3	Level 4	Level 5
Glucose	Precision Xceed Pro Blood Glucose Test Strip	mg/dL	25	97	260	347	444
Ketone	Precision Xceed Pro Blood β-Ketone Test Strip	mmol/L	0.4	1.1	2.4	3.6	5.1

RNA Medical Glucose and β-Ketone Calibration Verification Control is non-hazardous aqueous solution containing no biological materials.

(5) Intended use of the device

RNA Medical Glucose and β-Ketone Calibration Verification Control is intended to confirm the calibration and linearity of glucose and β-ketone of the Abbott Diabetes Care Precision Xceed Pro™ Blood Glucose and β-Ketone Monitoring System by healthcare professionals.

(6) Technological characteristics of the device.

This material is comprised of an aqueous solution of glucose (0.03% - 0.40%), β-hydroxybutyrate (0.01% - 0.12%), and non-reactive ingredients (viscosity enhancing agent, dye, buffer, and preservative) prepared in five specific glucose and ketone concentrations. These controls contain no hazardous or human biological materials.

[3] EDMS014536 Rev. 001, Summary of Expected G3CH And Ketones II Values for Bionostics Calibration Verification Control Solutions

(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) Use-life stability (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

OCT 0 6 2008

Bionostics, Inc.
c/o Ms. Kathleen Storro
Senior Director of Quality Affairs/
Regulatory Affairs
7 Jackson Road
Devens, MA 01434

Re: k081478
Trade Name: RNA Medical Glucose and ß-Ketone Calibration Verification Controls
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I, reserved
Product Code: JJX
Dated: September 10, 2008
Received: September 12, 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): K081478

Device Name: RNA Medical Glucose and β-Ketone Calibration Verification Controls

Indication For Use:

RNA Medical® Brand Glucose and β-Ketone Calibration Verification Controls are assayed materials for confirming the calibration and linearity of glucose and β-ketone at the upper and lower limits of the reportable range and at three (3) points within the range. This product is for use with the Precision Xceed Pro Blood Glucose and β-ketone Monitoring System, which uses Precision Xceed Pro Blood Glucose Test Strips and Precision Xceed Pro Blood β-Ketone Test Strips. It is not for use with the Precision PCx™ System or the i-STAT® 1 Analyzer, which use Precision PCx Test Strips, Precision PCx Plus Test Strips, or i-STAT 1 glucose cartridges.

RNA Medical Glucose and β-Ketone Calibration Verification Controls is intended for use by healthcare professionals.

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)

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

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