K103553

BIONOSTICS
Quality Solutions

FEB 1 0 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: 10 February 2011

(2) Device trade or proprietary name: LifeScan OneTouch Select Control Solution
LifeScan OneTouch Ultra Control Solution
LifeScan OneTouch Vita Control solution

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. Substantial Equivalence

LifeScan OneTouch Select, Ultra and Vita Control Solutions are 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	Proposed Device
Name:	OneTouch Ultra Control	OneTouch Select Control OneTouch Ultra Control OneTouch Vita Control
510(k), Date:	K022769, 11.13.2002	
Number of levels:	1, typical fasting glucose	1, typical fasting glucose
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:	OneTouch Ultra, OneTouch Select, OneTouch Vita	Unchanged: OneTouch Ultra, OneTouch Select, OneTouch Vita

LifeScan, OneTouch, OneTouch Ultra, OneTouch Select and OneTouch Vita are registrered trademarks of Johnson & Johnson Corporation, New Brunswick, NJ, USA.

[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

The control solution 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 primary differences in the composition of the OneTouch Select, Ultra and Vita branded Control Solutions to that of the current, OneTouch Ultra Control are the type and relative content of buffer system, type and relative content of the viscosity adjusting agent, type and relative content of the preservative system, a lower concentration of dye, and a relative reduction in the content of water. The OneTouch Ultra control is currently in use with all LifeScan blood glucose test systems under the OneTouch Ultra, OneTouch Select and OneTouch Vita brands. The new control solution is reformulated for optimized performance across these various brands of test strips, and will be distributed under the same brands as the current Ultra control.

(a) (1) Intended use of the device

LifeScan OneTouch Ultra Control Solution is intended for use to verify the performance of the LifeScan OneTouch Ultra Family and the OneTouch Ping™ Meter Remote blood glucose monitoring test systems at a glucose level printed on the test strip vial. The LifeScan OneTouch Ultra Control Solution is intended for use by healthcare professionals and people with diabetes mellitus at home.

LifeScan OneTouch Select Control Solution is intended for use to verify the performance of the LifeScan OneTouch Select blood glucose monitoring test system at a glucose level printed on the test strip vial. The LifeScan OneTouch Select Control Solution is intended for use by healthcare professionals and people with diabetes mellitus at home.

LifeScan OneTouch Vita Control Solution is intended for use to verify the performance of the LifeScan OneTouch Vita blood glucose monitoring test system at a glucose level printed on the test strip vial. The LifeScan OneTouch Vita Control Solution 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 single concentration of D-glucose with recovery on the test systems in the range typically considered normal, fasting glucose for a non-diabetic person. This solution has been optimized to simulate the response of whole blood on the LifeScan OneTouch Ultra, Select and Vita branded 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) 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

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FEB 10 2011

Bionostics, Inc.
c/o Randy Byrd
Vice President & Chief Technical Officer
7 Jackson Road
Devens, MA 01434

Re: k103553
Trade Name: LifeScan OneTouch Select Control Solution, LifeScan OneTouch Ultra Control Solution, LifeScan OneTouch Vita Control Solution
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material
Regulatory Class: Class I, reserved
Product Code: JJX
Dated: December 2, 2010
Received: December 3, 2010

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 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 Parts 801 and 809), 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 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/cdrh/industry/support/index.html.

Sincerely yours,

Courtney 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: K103553

Device Name: LifeScan® OneTouch® Select® Control Solution

Indications for Use: The LifeScan OneTouch Select Control Solution is intended for use to verify the performance of the LifeScan OneTouch Select blood glucose monitoring test system at a glucose level printed on the test strip vial. The LifeScan OneTouch Select Control Solution 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)

Carol C Benson

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

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Indications for Use

510(k) Number: K103553

Device Name: LifeScan® OneTouch® Ultra® Control Solution

Indications for Use: The LifeScan OneTouch Ultra Control Solution is intended for use to verify the performance of the LifeScan OneTouch Ultra Family and the OneTouch Ping™ Meter Remote blood glucose monitoring test systems at a glucose level printed on the test strip vial. The LifeScan OneTouch Ultra Control Solution 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)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K103553

Indications for Use

510(k) Number: K103553

Device Name: LifeScan® OneTouch® Vita® Control Solution

Indications for Use: The LifeScan OneTouch Vita Control Solution is intended for use to verify the performance of the LifeScan OneTouch Vita blood glucose monitoring test system at a glucose level printed on the test strip vial. The LifeScan OneTouch Vita Control Solution 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)

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