K083549

DEC 22 2008

5. 510(k) Summary

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:
American Biological Technologies, Inc. (AbT)
940 Crossroads Blvd
Seguin, TX 78155
(830) 372-1391 ex. 210
Establishment Registration Number: 1643621

Contact Person: John C. Gormley

Device Name: AbT Glucose Control Solution

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

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

Classification: Class I per 21 CFR 862.1660

Product Code: 75 JJX

Panel: Chemistry

Predicate Devices:

Name:	Freestyle Control Solution
Manufacturer:	Abbott Diabetes Care, Inc.
510(k) No.:	k031260
Name:	Liberty Glucose Control
Manufacturer:	Liberty Healthcare Group
510(k) No.:	k060481

Device Description: The AbT Glucose Control Solution consists of a viscosity-adjusted, aqueous liquid control solution containing a known quantity of glucose. The product is packaged in plastic dropper tipped bottles for easy application of the control solutions to the test strips and a red coloration to aid the user to visually confirm application of the control. The product is non-hazardous and contains no human or animal derived materials.

Intended Use: The AbT Glucose Control Solution is intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of FreeStyle and FreeStyle *Lite* Blood Glucose Monitor.

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Comparison to Predicate Device:

Characteristic/ Aspect	Predicate Device No. 1	Predicate Device No. 2	New Product
Name	FreeStyle Control Solution	Liberty Glucose Control	AbT Glucose Control Solution
510(k), Date	K031260, 12/19/2003	K060481, 3/09/2006	
Number of Levels	1	1	1
Analyte	Glucose	Glucose	Glucose
Target (mg/dL)	88	88	88
Target Range (mg/dL)	80 – 130[(1)]	80 – 130[(2)]	80 – 130
Container	Plastic bottle with dropper-tip	Plastic bottle with dropper-tip	Plastic bottle with dropper-tip
Fill Volume	4.0 mL	3.6 mL	3.6 mL
Color	Red	Red	Red
Matrix	Buffered aqueous solution of D-Glucose, viscosity modifier, preservatives, and other non-reactive ingredients	Buffered aqueous solution of D-Glucose, a viscosity modifier, preservatives, and other non-reactive ingredients	Identical to Predicate 2 which is manufactured by AbT.
Indications for Use	For use with the FreeStyle blood glucose monitoring system in order to ensure that the FreeStyle meter and FreeStyle test strips are working properly.	Used to check the performance of FreeStyle Blood Glucose Systems.	Used to check the performance of FreeStyle and FreeStyle *Lite* Blood Glucose Systems.
Target Population	Professional and home use	Professional and home use	Professional and home use

[(1)]Estimated using published control ranges assigned by the manufacturer for several lots of FreeStyle *Lite* test strips.

[(2)]AbT's target range for the Liberty Glucose Control.

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

1. Stability
2. Open Vial
3. Mean and Variance Comparison

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
2098 Gaither Road
Rockville MD 20850

American Biological Technologies, Inc.
c/o John Gormley
Director of Quality and Regulatory Affairs
940 Crossroads Blvd.
Seguin, TX 78155

DEC 22 2008

Re: k083549
Trade Name: AbT Glucose Control Solution
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (assayed and unassayed).
Regulatory Class: Class I, reserved
Product Codes: JJX
Dated: December 1, 2008
Received: December 1, 2008

Dear Mr. Gormley:

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

4. Indications for Use Statement

510(k) Number (if known): K083549

Device Name: AbT Glucose Control Solution

Indications for Use:

For in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the FreeStyle and FreeStyle *Lite* Blood Glucose Monitors.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

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

510(k) K083549