

K080273

510(k) Premarket Notification: FDTX Glucose Control Solution  
Fujirebio Diagnostics, Texas, Inc.

AUG - 8 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:** Fujirebio Diagnostics Texas Inc.  
940 Crossroads Blvd  
Seguin, TX 78155  
(830) 372-1391 ex. 210  
Establishment Registration Number: 1643621

**Contact Person:** John C. Gormley

**Device Name:** FDTX 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:	Bayer Ascensia BREEZE 2 Normal Control
Manufacturer:	Bayer Healthcare, LLC.
510(k) No.:	K062347
Name:	Liberty Normal Glucose Control Solution
Manufacturer:	Liberty Healthcare Group
510(k) No.:	K060426

**Device Description:** The FDTX 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 FDTX 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 Bayer Ascensia BREEZE 2 Blood Glucose Monitor.

**Comparison to Predicate Device:**

Characteristic/ Aspect	Predicate Device No. 1	Predicate Device No. 2	New Product
Name	Ascensia <i>BREEZE</i> 2 Control Normal	Liberty Glucose Normal Control Solution	FDTX Glucose Control Solution
510(k), Date	K062347, 11/21/2006	K060426, 3/09/2006	k080273
Number of Levels	1	1	1
Analyte	Glucose	Glucose	Glucose
Target (mg/dL)	100	100	100
Target Range (mg/dL)	85 – 130	113 – 170	85 – 130
Container	Plastic bottle with dropper-tip	Plastic bottle with dropper-tip	Plastic bottle with dropper-tip
Fill Volume	2.5 mL	3.6 mL	3.6 mL
Color	Blue	Red	Red
Matrix	Blue solution containing a measured amount of glucose.	Buffered aqueous solution of D-Glucose, a viscosity modifier, preservatives, and other non-reactive ingredients	Buffered aqueous solution of D-Glucose, a viscosity modifier, preservatives, and other non-reactive ingredients
Indications for Use	For use as quality control check to verify that the BREEZE 2 meter and test strips are working properly.	To check the performance of the Bayer Ascensia DEX 2/DEX and BREEZE Blood Glucose Monitors.	To check the performance of the Bayer Ascensia BREEZE 2 Blood Glucose Monitor.
Target Population	Professional and home use	Professional and home use	Professional and home use

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

1. Stability
2. Open Vial
3. Test precision

**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

Fujirebio Diagnostics Texas, Inc  
c/o Mr. John Gormley, Director of Quality  
& Regulatory Affairs  
940 Crossroads Boulevard  
Seguin, TX 78155

**AUG - 8 2008**

Re: K080273  
Trade/Device Name: FDTX Glucose Control Solution  
Regulation Number: 21 CFR 862.1660  
Regulation Name: Quality Control Material (assayed and unassayed)  
Regulatory Class: Class I, reserved  
Product Code: JJX  
Dated: June 17, 2008  
Received: June 17, 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).

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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

510(k) Premarket Notification: FDTX Glucose Control Solution  
Fujirebio Diagnostics, Texas, Inc.

**4. Indications for Use Statement**

510(k) Number (if known): k080273

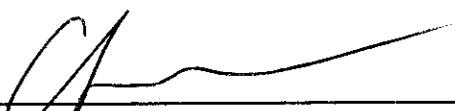
Device Name: FDTX Glucose Control Solution

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 BREEZE 2 Blood Glucose Monitor.

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)

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

510(k)  K080273