K081915

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:	Ascensia Microfill Control Solution
Manufacturer:	Bayer Healthcare
510(k) No.:	K023657

Name:	Liberty Normal Glucose Control Solution
Manufacturer:	Liberty Healthcare Group
510(k) No.:	K060706

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 CONTOUR Blood Glucose Monitor.

Comparison to Predicate Devices:

Characteristic/ Aspect	Predicate Device No. 1	Predicate Device No. 2	New Product
Name	Ascensia Contour/Microfill Control Solution	Liberty Normal Glucose Control	FDTX Glucose Control Solution
510(k), Date	K023657 05/12/2003	K060706, 04/28/2006	
Number of Levels	1	1	1
Analyte	Glucose	Glucose	Glucose
Target Range (mg/dL)	100 – 143[(1)]	90 – 130[(2)]	100 - 145
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	Red	Red	Red
Matrix	Aqueous Glucose solution.	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 with the Ascensia Contour Blood Glucose Meter and the Ascensia *MICROFILL* Test Strips as a quality control check.	To check the performance of OneTouch Ultra, OneTouch FastTake, Accu-Chek Active, and Ascensia Contour Blood Glucose Systems.	To check the performance of the Ascensia Contour Blood Glucose System.
Target Population	Professional and home use	Professional and home use	Professional and home use

[(1)]Estimated from published control ranges assigned by the manufacturer for several lots of Contour test strips.

[(2)]Estimated from published control ranges assigned by the manufacturer for several lots of Liberty Normal Glucose Control.

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

1. Accelerated 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: K081915
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 27, 2008
Received: July 3, 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): K081915

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 Contour 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) K081915