K092645

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

SEP 25 2009

Contact Person: John C. Gormley

Device Name: FDI Glucose Controls Levels 1, 2. and 3

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:	TRUEcontrol Glucose Control Levels 0, 1, and 2
Manufacturer:	Home Diagnostics, Inc.
510(k) No.:	k030703

Device Description: The FDI Glucose Controls consist of a viscosity-adjusted, aqueous liquid control solutions containing known quantities 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 FDI Glucose Controls are 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 the TrueTrack®, TrackEASE® and TRUEread™ meters and test strips.

Comparison to Predicate Devices:

Characteristic/ Aspect		Predicate Device		New Product
Name		TRUEcontrol Glucose Control		FDI Glucose Controls
510(k), Date		K030703 08/11/2003		
Number of Levels		3		3
Analyte		Glucose		Glucose
Target Range (mg/dL)	0	83 – 121[1]	1	81 – 121[2]
	1	173 – 256[1]	2	172 – 257[2]
	2	341 - 516[1]	3	328 – 490[2]
Container		Plastic bottle with dropper-tip		Plastic bottle with dropper-tip
Fill Volume		3.0 mL		3.6 mL
Color		Red		Red
Matrix		Water, D-glucose, buffers, viscosity enhancing agents, inorganic salts, amaranth, and preservatives.		Buffered aqueous solution of D-Glucose, a viscosity modifier, preservatives, and other non-reactive ingredients
Indications for Use		To check the performance the TrueTrack®, TrackEASE® and TRUEread™ meters and test strips		To check the performance of the TrueTrack®, TrackEASE® and TRUEread™ meters and test strips
Target Population		Professional and home use		Professional and home use

[1] Estimated from the manufacturer's published control ranges.

[2]Based on a +/- 5% glucose concentration variability lot-to-lot and +/- 15% range

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

1. Accelerated and Real-time 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

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

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

SEP 25 2009

Re: k092645
Trade Name: FDI Glucose Controls Levels 1, 2 and 3
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material (assayed and unassayed).
Regulatory Class: Class I, Reserved
Product Codes: JJX
Dated: August 25, 2009
Received: August 27, 2009

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); 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 Part 801), 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. 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

4 Indications for Use Statement

510(k) Number (if known): K092645

Device Name: FDI Glucose Controls

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 TrueTrack®, TrackEASE® and TRUEread™ meters and test strips.

Prescription Use __X__ (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use __X__ (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) k092645