K 111874

FEB 16 2012

510(k) Summary

According to the requirements Per 21 CFR §807.92, the following information is provides sufficient detail to understand the basis for a determination of substantial equivalence.

Company:	Abbott Laboratories
Division:	Abbott Diabetes Care, Inc.
Street Address:	1360 South Loop Road
City, State Zip:	Alameda, CA 94502
Telephone No:	510-749-5400
Fax No:	510-864-4791
Contact Person:	Arul Sterlin; Tel No. 510-864-4310; Fax No. 510-864-4791; arul.sterlin@abbott.com
Proprietary Name:	FreeStyle InsuLinx Blood Glucose Monitoring System
Common Name:	Glucose Test System
Classification Name:	Glucose Dehydrogenase, Glucose, Class II (21 CFR§ 862.1345) Product codes: NBW; Glucose Dehydrogenase, Glucose, Class II (21 CFR§ 862.1345) Product codes: LFR;
Predicate Device:	FreeStyle Tracker Diabetes Management (k020866)
Legal Manufacturer:	Establishment: Abbott Diabetes Care Inc. 1360 South Loop Rd. Alameda, CA 94502 Registration Number: 2954323

Indications For Use:

The FreeStyle InsuLinx Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip. The FreeStyle InsuLinx Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The FreeStyle InsuLinx Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The FreeStyle InsuLinx Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use.

The FreeStyle InsuLinx Blood Glucose Test Strips are for use with the FreeStyle InsuLinx Blood Glucose Meter to quantitatively measure glucose in capillary whole blood samples drawn from the fingertip.

FreeStyle Control Solutions are for use with the FreeStyle InsuLinx Blood Glucose Monitoring System as a quality control check to verify the accuracy of blood glucose test results.

Description of the Device:

The FreeStyle InsuLinx Meter, in conjunction with the FreeStyle InsuLinx Test Strips works on the principal of coulometric biosensor technology, measuring glucose by its reaction with Glucose Dehydrogenase (GDH) in blood samples or control solutions, through electrochemical mediation.

The device automatically logs blood glucose results and other events to create a customized logbook. The FreeStyle InsuLinx System has a large touch screen and a user interface designed for an easy user experience.

Patient and Healthcare Professionals can pre-program audible and visual reminders for blood glucose testing, or other individual needs.

Weekly messages feature assist the patient in identifying patterns in their blood glucose results. Using a rolling report, the measured glucose values are summarized according to the proportion within, above, or below the predetermined target range entered by the patient or HCP. These results are displayed in a simple graphical format and include a count of the tests performed. An additional algorithm compares the prevailing blood glucose levels during the preceding week with simple messages relating to achievement versus target glucose levels.

The FreeStyle InsuLinx System has 'plug and play' software that automatically installs on a computer without the need for a CD or internet access (via the meter's USB port and a provided cable). It also provides access to the structured reports for both the healthcare professionals and patients.

The FreeStyle Auto-Assist software produces six different reports to facilitate discussion between patients and their health care professionals in the review, analysis, and evaluation of historical blood glucose test results to support an effective diabetes management program. The software also shows trends in blood glucose data in both graphical and text format for guided interpretation.

- The **Snapshot Report** is a general summary of the data for a specified date range.
- The **Modal Day Report** shows the daily patterns of blood glucose levels over a specified date range
- The **Logbook Report** is a table of blood glucose for each day in the specified date range.
- The **Daily Statistics Report** provides an overview of blood glucose over the date range in a series of charts and tables.
- The **Meal Event Averages Report** compares the before and after meal blood glucose level averages for the morning, mid-day and evening times over the specified date range.
- The **Meter Settings Report** shows current meter settings.

These reports provide detailed information on glucose monitoring, and are designed to enable healthcare professionals and patients to assess the effectiveness of diabetes management and then plan appropriate changes to therapy regimens.

The FreeStyle InsuLinx System may be packaged within a cardboard carton, in addition to the following components and accessories listed below.

(A) FreeStyle InsuLinx Meter

(B) 10 count vial of FreeStyle InsuLinx Test Strips (may be sold separately)

(C) FreeStyle Auto-Assist software (resides in the FreeStyle InsuLinx Meter)

(D) Carrying Case

(E) Owner's Booklet

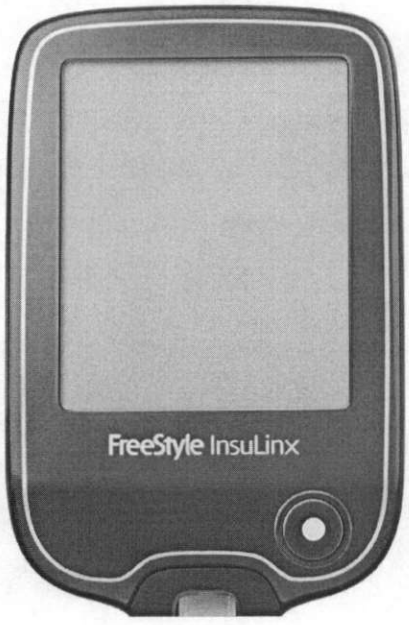
(F) Quick Start Guide

(G) USB Cable

(H) FreeStyle Control Solutions (may be obtained by contacting Customer Service)

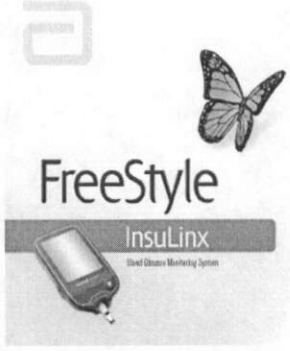
Figure 1 – FreeStyle InsuLinx System Components and Accessories

(A)

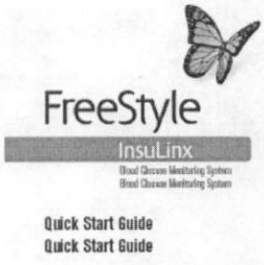


(B)

(C)



Owner's Booklet

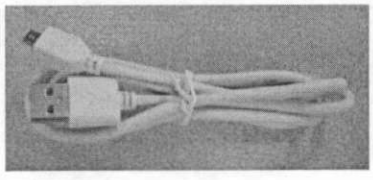


(E)

Quick Start Guide
Quick Start Guide

(F)

(D)



(G)

(H)

Principles of Operation:

The FreeStyle InsuLinx Meter (in conjunction with FreeStyle InsuLinx blood glucose test strips) utilizes coulometric biosensor technology to quantitatively measure the glucose concentration in whole blood samples and in FreeStyle Control Solutions.

The FreeStyle InsuLinx Meter measures glucose electrochemically. The glucose biosensor is capable of recognizing the glucose present in whole blood or control solutions by virtue of the glucose specificity of the enzyme glucose dehydrogenase (GDH) present on the glucose test strip. The electrons liberated by this reaction are transferred via a co-factor and mediator to the meter where they are read as a small electrical current. The current is integrated over the analysis time to generate charge which is directly proportional to the level of the glucose in the applied sample.

The FreeStyle InsuLinx Meter does not require calibration prior to use with the FreeStyle InsuLinx Test Strips. The device is prepared for use by inserting a FreeStyle InsuLinx test strip in the test strip port. Upon strip insertion, the meter will turn on automatically and perform a display check. The 'apply blood' message is displayed for the user to apply blood to the test strip until the meter begins the test. Blood detect will occur when the meter detects trigger current from the test strip, when enough blood has covered the strip electrodes. Following the blood detect, the meter performs the glucose assay measurement.

Comparison to Predicate Device:

The similarities between FreeStyle InsuLinx System and the predicate are highlighted below:

PRODUCT NAME	FreeStyle InsuLinx Blood Glucose Monitoring System (K111874)	Freestyle Tracker Diabetes Management System (K020866)
CHARACTERISTICS		
Classification Product Code	NBW, LFR, JJX	NBW, LFR
Fundamental Technology	The FreeStyle InsuLinx Meter (in conjunction with blood glucose test strips) utilizes coulometric biosensor technology to quantitatively measure the glucose concentration in whole blood samples and in FreeStyle Control Solutions	The FreeStyle Tracker Meter (in conjunction with blood glucose test strips) utilizes coulometric biosensor technology to quantitatively measure the glucose concentration in whole blood samples and in FreeStyle Control Solutions
Sample Volume	0.3 µL	0.3 µL
Measurement Glucose Range	20 to 500 mg/dL	20 to 500 mg/dL
Meter Operating Humidity	5 to 90% Relative Humidity, Non-Condensing	5 to 90% Relative Humidity, Non-Condensing
Storage Operating Temperature	-4°F to 140°F (-20°C to +60°C)	-4°F to 140°F (-20°C to +60°C)
Precision	At glucose levels below 75mg/dL average SD is ≤ 5mg/dL and at glucose levels ≥ 75mg/dL average CV is ≤ 5%	At glucose levels below 75mg/dL average SD is ≤ 5mg/dL and at glucose levels ≥ 75mg/dL average CV is ≤ 5%
Accuracy	95% of results should fall within ± 15mg/dL of the comparative method results at glucose concentrations < 75mg/dL and within ±20% at glucose concentrations ≥	95% of results should fall within ± 15mg/dL of the comparative method results at glucose concentrations < 75mg/dL and within ±20% at glucose

PRODUCT NAME	FreeStyle InsuLinx Blood Glucose Monitoring System (K111874)	Freestyle Tracker Diabetes Management System (K020866)
	75 mg/dL	concentrations ≥ 75 mg/dL
Double Application	60 seconds	60 seconds

The differences between FreeStyle InsuLinx System and the predicate are highlighted below:

PRODUCT NAME	FreeStyle InsuLinx Blood Glucose Monitoring System (K111874)	Freestyle Tracker Diabetes Management System (K020866)
CHARACTERISTICS		
Indications for Use	The FreeStyle InsuLinx Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip. The FreeStyle InsuLinx Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The FreeStyle InsuLinx Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The FreeStyle InsuLinx Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use. The FreeStyle InsuLinx	The TheraSense, Inc., FreeStyle Tracker Diabetes Management System is intended for use in the quantitative measurement of glucose in whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. Additionally, the TheraSense, Inc. FreeStyle Tracker Diabetes Management System is intended for use in home and clinical setting to aid people with diabetes

PRODUCT NAME	FreeStyle InsuLinx Blood Glucose Monitoring System (K111874)	Freestyle Tracker Diabetes Management System (K020866)
	Blood Glucose Test Strips are for use with the FreeStyle InsuLinx Blood Glucose Meter to quantitatively measure glucose in capillary whole blood samples drawn from the fingertip. FreeStyle Control Solutions are for use with the FreeStyle InsuLinx Blood Glucose Monitoring System as a quality control check to verify the accuracy of blood glucose test results.	and healthcare professionals in the review, analysis, and evaluation of historical blood glucose test results to support an effective diabetes management program. The TheraSense, Inc. FreeStyle Tracker Diabetes Management System is specifically indicated for use on the finger, forearm, upper arm, thigh, calf and hand.
Enzyme	GDH – FAD	GDH - PQQ
Sample Type	Whole blood, capillary & venous,	Whole blood, capillary
Test Sites	Finger	Finger, forearm, upper arm, thigh, calf and hand
Data Management	FreeStyle Auto-Assist software	FreeStyle Connect Blood Glucose Monitoring System (K051802)
Measurement Module	FreeStyle Super Speedy Algorithm (5 seconds)	FreeStyle Speedy Algorithm (15 seconds)
Application Software	Software running on the meter provides the User with an Electronic Logbook, Data Management and Diabetes Management Tools	Software running on the PDA provides the User with an Electronic Logbook, Data Management and Diabetes Management tools
Measurement Time	average 5 seconds	average of 15 seconds
Meter Firmware Operating System version	The Auto-Assist software is compatible with Windows 7 Home	The PDA Meter Firmware is compatible with

PRODUCT NAME	FreeStyle InsuLinx Blood Glucose Monitoring System (K111874)	Freestyle Tracker Diabetes Management System (K020866)
	Premium.	version 3.1 or newer versions of the Palm OS as delivered in HandSpring PDAs.
Meter Firmware Upgrade Or Modification	N/A	The PDA Meter Firmware is not User modifiable or field upgradeable
Setting Meter Preferences	The device lets the User set preferences of time format, and On or Off audible alerts.	The device lets the User set preferences of units of measure, date format, time format, and audible alert level.
Application Switch Before Measurement Complete	N/A	The User can attempt to switch to another application program during a glucose measurement, and the glucose measurement is completed and saved, if possible.
Coding	No coding required	Coding required
Microprocessor	ST	TI
Database Synchronization	N/A	The PDA Application enables the user to select/specify the Measurement Module database (i.e., the last 250 Glucose measurements performed by the Measurement Module) to be downloaded from the Measurement Module and merge with the existing PDA database (if any exists). When the PDA has no database but has a Database ID (signifying an existing

PRODUCT NAME	FreeStyle InsuLinx Blood Glucose Monitoring System (K111874)	Freestyle Tracker Diabetes Management System (K020866)
		User), the PDA Application prompts the User to restore the PDA database from a PC back-up prior to performing the database synchronization with the Measurement module database.
User Preferences	The device lets the user set: • Time and Date Changes • Time and Date Formats • Audible Alert • Personalized test screen • Weekly Message glucose ranges • Personalized notes and reminders	The device lets the user set: • Corrupt/Missing Preference Detection • Concentration Units • Time and Date Changes • Time and Date Formats • Audible Alert • Tracking exercise • Tracking Insulin • Tracking Pump (Basal Rate) • Tracking Medication • Tracking Meal/Carbohydrate • Tracking State of Health • Default Event Tracking • Basal Tracking
Summary Statistic Elements	• Snapshot Report • Modal Day Report • Logbook Report • Daily Statistics Report • Meal Event Averages Report	• Highest Reading Date • Lowest Reading Date • Carbohydrate Statistics

PRODUCT NAME	FreeStyle InsuLinx Blood Glucose Monitoring System (K111874)	Freestyle Tracker Diabetes Management System (K020866)
	• Meter Settings Report • Weekly messages	• Insulin Statistics • Basal Insulin Statistics • Glucose Line Graph • Glucose Readings Pie Chart • Modal Day Chart
Diabetes Management Tools	N/A	• Carbohydrate table • Insulin tables • Prescribed Regimen (food and exercise patterns) • Basal Rate Schedule • Target glucose level
Communications	"Plug and Play" device set-up screen that enables configuration of the device through the PC	The HotSync protocol is used to transfer data to and from a PC
PC Utility Software	The PC Utility Software is capable of running on an IBM-PC compatible software	The PC Utility Software is capable of running on an IBM-PC compatible software
Meter Operating Temperature	40°F to 104°F (4°C to 40°C)	50°F to 95°F (10°C to 35°C)
Meter Operating Pressure	Up to 10000 feet (3048 meters)	10.15 psi to 15.4 psi (700 hPa to 1060 hPa, 20,000 ft to sea level)
Hematocrit	15% - 65%	0 - 60%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Abbott Laboratories
c/o Arul Sterlin
Senior Regulatory Affairs Specialist
1360 South Loop Road
Alameda, CA 94502

FEB 16 2012

Re: k111874
Trade Name: FreeStyle InsuLinx Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, LFR
Dated: February 14, 2012
Received: February 15, 2012

Dear Mr. Sterlin:

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 H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k111874

Device Name: FreeStyle InsuLinx Blood Glucose Monitoring System

Indications For Use:

The FreeStyle InsuLinx Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip. The FreeStyle InsuLinx Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

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The FreeStyle InsuLinx Blood Glucose Test Strips are for use with the FreeStyle InsuLinx Blood Glucose Meter to quantitatively measure glucose in capillary whole blood samples drawn from the fingertip.

Prescription Use _____ And/Or Over the Counter Use __X__
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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

510(k) k111874