



September 17, 2015

ABOTT LABORATORIES  
SAI TATAVARTY  
REGULATORY AFFAIRS SPECIALIST  
1360 SOUTH LOOP ROAD  
ALAMEDA CA 94502

Re: K152328

Trade/Device Name: Freestyle InsuLinx Blood Glucose Monitoring System  
Regulation Number: 21 CFR 862.1345  
Regulation Name: Glucose test system  
Regulatory Class: II  
Product Code: NBW, LFR  
Dated: August 17, 2015  
Received: August 18, 2015

Dear Ms. Tatavarty:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
**Katherine Serrano -S**

For: Courtney H. Lias  
Director  
Division of Chemistry and Toxicology Devices  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K152328

Device Name  
FreeStyle InsuLinx Blood Glucose Monitoring System

### Indications for Use (Describe)

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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)       Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

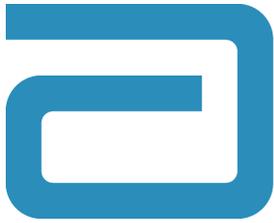
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**510(k) Summary**

According to the requirements per 21 CFR §807.92, the following information 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
Contact Person:	Sai Sriharshada Tataavarty Tel No. 510-749-5105 Fax No. 510-864-4791 sai.tatavarty@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,LFR
Predicate Device:	FreeStyle InsuLinx Blood Glucose Monitoring System (k120568)
Legal Manufacturer:	Establishment: Abbott Diabetes Care Inc. 1360 South Loop Road Alameda, CA 94502

**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.

**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 to create a customized logbook. The FreeStyle InsuLinx System has a large touch screen and a user interface designed for an easy user experience.

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

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.

**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.

**Description of Modification:**

The basis for this submission is to include the FreeStyle Lancing Device II into the FreeStyle InsuLinx System kit, which may be packaged with 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)

**Substantial Equivalence:**

The FreeStyle InsuLinx Blood Glucose Monitoring System is substantially equivalent to the predicate, which was cleared by the Agency on March 29, 2012, to market under k120568: FreeStyle InsuLinx Blood Glucose Monitoring System. The results obtained from performance studies demonstrate that the FreeStyle InsuLinx Blood Glucose Monitoring System is safe and effective for its intended use and technological characteristics, and therefore, substantially equivalent to the predicate device (k120568).

**Comparison to Predicate Device:**

The similarities and differences between the FreeStyle InsuLinx Blood Glucose Monitoring System and the predicate (k120568) are highlighted in the table below.

**Similarities:**

<b>PRODUCT NAME</b>	<b>FreeStyle InsuLinx Blood Glucose Monitoring System (K120568)</b>	<b>Modified FreeStyle InsuLinx Blood Glucose Monitoring System</b>
<b>CHARACTERISTICS</b>		
<b>Indications for Use</b>	<p>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.</p> <p>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.</p> <p>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.</p>	Same

<b>PRODUCT NAME</b>	<b>FreeStyle InsuLinx Blood Glucose Monitoring System (K120568)</b>	<b>Modified FreeStyle InsuLinx Blood Glucose Monitoring System</b>
<b>Classification Product Code</b>	NBW, LFR	Same
<b>Fundamental Technology</b>	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	Same
<b>Enzyme</b>	GDH – FAD	Same
<b>Sample Type</b>	Whole blood & capillary	Same
<b>Test Sites</b>	Finger	Same
<b>Sample Volume</b>	0.3 µL	Same
<b>Measurement Glucose Range</b>	20 to 500 mg/dL	Same
<b>Meter Operating Humidity</b>	5 to 90% Relative Humidity, Non-Condensing	Same
<b>Storage Operating Temperature</b>	-4°F to 140°F (-20°C to +60°C)	Same
<b>Precision</b>	At glucose levels below 75mg/dL average SD is ≤ 5mg/dL and at glucose levels ≥ 75mg/dL average CV is ≤ 5%	Same
<b>Accuracy</b>	95% of results should fall within ± 15mg/dL of the comparative method results at glucose concentrations < 75mg/dL and within ±20% at glucose concentrations ≥ 75	Same

<b>PRODUCT NAME</b>	<b>FreeStyle InsuLinx Blood Glucose Monitoring System (K120568)</b>	<b>Modified FreeStyle InsuLinx Blood Glucose Monitoring System</b>
	mg/dL	
<b>Measurement Module</b>	FreeStyle Super Speedy Algorithm (5 seconds)	Same
<b>Double Application</b>	60 seconds	Same
<b>Meter Operating Temperature</b>	40°F to 104°F (4°C to 40°C)	Same
<b>Meter Operating Pressure</b>	Up to 10000 feet (3048 meters)	Same
<b>Hematocrit</b>	15% - 65%	Same
<b>Data Management</b>	FreeStyle Auto-Assist software	Same
<b>Measurement Time</b>	Average 5 seconds	Same
<b>Coding</b>	No coding required	Same
<b>Microprocessor</b>	ST	Same
<b>User Preferences</b>	The device lets the user set: <ul style="list-style-type: none"> <li>• Time and Date Changes</li> <li>• Time and Date Formats</li> <li>• Audible Alert</li> <li>• Personalized test screen</li> <li>• Weekly Message glucose ranges</li> <li>• Personalized notes and reminders</li> </ul>	Same
<b>Summary Statistic Elements</b>	<ul style="list-style-type: none"> <li>• Snapshot Report</li> <li>• Modal Day Report</li> <li>• Logbook Report</li> </ul>	Same

<b>PRODUCT NAME</b>	<b>FreeStyle InsuLinx Blood Glucose Monitoring System (K120568)</b>	<b>Modified FreeStyle InsuLinx Blood Glucose Monitoring System</b>
	<ul style="list-style-type: none"> <li>• Daily Statistics Report</li> <li>• Meal Event Averages Report</li> <li>• Meter Settings Report</li> <li>• Weekly messages</li> </ul>	
<b>Communications</b>	“Plug and Play” device set-up screen that enables configuration of the device through the PC	Same
<b>Lancets</b>	FreeStyle/Thin Lancets	Same

**Differences:**

<b>PRODUCT NAME</b>	<b>FreeStyle InsuLinx Blood Glucose Monitoring System (K120568)</b>	<b>Modified FreeStyle InsuLinx Blood Glucose Monitoring System</b>
<b>CHARACTERISTICS</b>		
<b>Meter cleaning and disinfection</b>	522 cleaning and 522 disinfection cycles (equivalent to cleaning and disinfecting once a week over the 5-year service life) with Dispatch® Hospital Cleaner Disinfectant Towels with Bleach, EPA 56392-8	522 cleaning and 522 disinfection cycles (2 cycles per week for 5 years) with Clorox Healthcare Bleach Germicidal Wipes, EPA Reg. #67619-12
<b>Lancing device cleaning and disinfection</b>	522 cleaning and 522 disinfection cycles (equivalent to cleaning and disinfecting once a week over the 5-year service life) with Dispatch® Hospital Cleaner Disinfectant Towels with Bleach, EPA 56392-8	210 cleaning and 210 disinfection cycles (2 cycles per week for 2 years) with Clorox Healthcare Bleach Germicidal Wipes, EPA Reg. #67619-12
<b>Lancing device</b>	FreeStyle Lancing Device	FreeStyle Lancing Device-II