

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

k111874

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative, Amperometric Method, Glucose Dehydrogenase (FAD)

E. Applicant:

Abbott Laboratories

F. Proprietary and Established Names:

FreeStyle InsuLinx Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LFR Glucose dehydrogenase, glucose	Class II	21 CFR § 862.1345	Clinical Chemistry (75)
NBW system, test, blood glucose, over the counter	Class II	21 CFR § 862.1345	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

1. Indication(s) 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.

3. Special conditions for use statement(s):

- For over-the-counter use.
- Not intended for the diagnosis of or screening for diabetes mellitus.
- Not intended for use on neonates.
- For *in vitro* diagnostic use only
- Not for use on patients who are dehydrated, hypotensive, in shock, or for individuals in hyperglycemic-hyperosmolar state, with or without ketosis.
- Critically ill patients should not be tested with a blood glucose meter.
- The meter and its accessories are for use by a single person.

4. Special instrument requirements:

FreeStyle InsuLinx Blood Glucose Meter.

I. Device Description:

The FreeStyle InsuLinx Blood Glucose Monitoring System is comprised of the FreeStyle InsuLinx Blood Glucose Meter, FreeStyle InsuLinx Test Strips, Freestyle Auto-Assist software (resides in the FreeStyle InsuLinx Meter) and USB cable for data transmission.

J. Substantial Equivalence Information:

Predicate device name	Predicate 510(k) number
FreeStyle Tracker Diabetes Management	k020866

Comparison with predicate:

Similarities and Differences		
Item	Proposed Device FreeStyle InsuLinx Blood Glucose Meter	Predicate Device (k020866)
Intended Use	The quantitative measurement of glucose in capillary whole blood	Same
Enzyme-Cofactor	GDH-FAD	GDH-PQQ
Detection Method	Same	Amperometric method
Measurement Range	Same	20 to 500 mg/dL

Hematocrit Range	15 to 65%	0 to 60%
Sample Type	Capillary whole blood	Capillary whole blood
Test Sites	Finger	Finger, forearm, upper arm, thigh, calf and hand
Sample Volume	Same	>0.3 µl
Measurement Time	5 seconds	15 seconds
Altitude Limit	0 to 10,000 feet	0 to 20,000 feet
Meter Operating Temperature	40 to 104°F	50 to 95°F
Operating Humidity	Same	5 to 90%
Data Management	FreeStyle Auto-Assist	FreeStyle Connect Blood Glucose Monitoring System (k051802)
Application Software	Software provides the User with an Electronic Logbook and Data Management.	Software provides the User with an Electronic Logbook, Data Management and Diabetes Management tools

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP5-A2: Evaluation of Precision Performance of Quantitative Measurement Methods

CLSI EP6-A: Evaluation of Linearity of Quantitative Measurement

CLSI EP7-A2: Interference Testing in Clinical Chemistry.

ISO 15197: *In Vitro* Diagnostic Test Systems-Requirements for Blood Glucose Test Systems for Self Managing Diabetes Mellitus.

L. Test Principle:

The FreeStyle InsuLinx Meter, in conjunction with FreeStyle InsuLinx 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.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Within-run precision was measured by using five spiked venous whole blood

samples (hematocrit ranging from 35% to 50%). Each sample was tested on three lots of test strips on ten meters. Ten replicates were tested per meter, test strip lot, and glucose concentration, (n=100 tests per test strip lot). Results are summarized below:

Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
1	50	1.8	3.5
2	46	1.5	3.3
3	47	1.4	3.1
1	97	2.0	2.0
2	96	2.8	2.9
3	94	2.0	2.1
1	149	3.6	2.4
2	145	4.9	3.4
3	143	4.0	2.8
1	246	7.2	2.9
2	245	10.4	4.2
3	237	7.2	3.0
1	410	13.4	3.3
2	405	20.7	5.1
3	393	15.2	3.9

Between-day precision was measured by reading three levels of control solutions. Each sample was tested on three lots of test strips, twenty replicates per day for ten days using ten meters, (n=200 tests per test strip lot). Results are summarized below:

Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
1	55	1.3	2.3
2	53	1.7	3.2
3	52	1.6	3.1
1	103	2.1	2.1
2	101	2.8	2.7
3	99	2.3	2.3
1	306	7.0	2.3
2	296	7.6	2.6
3	297	7.8	2.6

b. Linearity/assay reportable range:

A linearity study was performed using nine spiked venous whole blood samples that covered the claimed measuring range. All samples were tested on six lots of test strips, ten measurements per test strip lot, on the FreeStyle InsuLinx Blood Glucose Meter. Glucose concentrations were tested on the

YSI 2300 analyzer to generate the expected values. The observed values were plotted against the expected values and an appropriate line fitted by standard linear regression was generated with results summarized below:

Linear Regression Analysis:

Lot 1:	$y = 0.98x + 4.2, r^2 = 0.997.$
Lot 2:	$y = 1.00x + 2.6, r^2 = 0.997.$
Lot 3:	$y = 0.99x + 5.2, r^2 = 0.997.$
Lot 4:	$y = 0.96x + 0.9, r^2 = 0.998.$
Lot 5:	$y = 0.99x + 1.3, r^2 = 0.996.$
Lot 6:	$y = 0.99x + 3.9, r^2 = 0.995.$

Based upon the results, the sponsor claims a measurement range of 20 to 500 mg/dL for the FreeStyle InsuLinx Blood Glucose Meter.

- c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
 The FreeStyle Control Solutions were previously cleared under k070850. Ranges for each control level are on the test strip vial labels.

FreeStyle InsuLinx Blood Glucose Test Strip used for the FreeStyle InsuLinx System is the renamed brand name for “FreeStyle Lite Test Strip” which was cleared under k092602. The test strip stability was assessed in real time study. The testing supports the claimed shelf life of 24 months when stored at 4-30°C in desiccated vials.

- d. *Detection limit:*
 The reportable range is 20 to 500 mg/dL based on linearity/reportable range studies above (section M.1.b.).

- e. *Analytical specificity:*
 The sponsor performed interference studies with spiked venous blood samples at two glucose concentrations (100 and 300 mg/dL) that were prepared and divided into a test (dosed) pool and a control pool. Studies were conducted using three FreeStyle InsuLinx Blood Glucose Meters and three lots of test strips. Significant interference is defined as a bias $\geq 10\%$ from the control group as measured on YSI 2300 analyzer. The sponsor claims no significant interference ($\leq 10\%$ difference) for the substances and concentrations shown in the table below:

Compound	Concentration with <10% interference (mg/dL)
Acetaminophen	20
Ascorbate	5
Beta-Hydroxybutyrate	100
Bilirubin (unconjugated)	20
Cholesterol	500
Creatinine	30

Dopamine	13
Ephedrine	10
Galactose	100
Ibuprofen	50
L-Dopa	5
Lactate	100
Lactose	100
Maltose	100
Methyl-Dopa	2.5
Pyruvate	10
Salicylic acid	50
Tetracycline	4
Tolazamide	100
Tolbutamide	100
Triglyceride	3000
Uric acid	40

Interference was observed with xylose at 100 mg/dL and is indicated in the test strip labeling.

- f. *Assay cut-off:*
Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

The sponsor conducted a combined accuracy and consumer study at two sites with trained operators and a total of 146 lay-users. Each lay user participant performed their own finger stick and tested their blood on the FreeStyle InsuLinx Blood Glucose meter using only the instructions in the Owner's Booklet and test strip insert. A trained operator then performed a second finger stick and tested the blood on the same meter. A whole blood sample from the subject's fingertip was collected by the trained operator for hematocrit determination and analysis on the YSI 2300 analyzer. The total range of samples tested was 33 to 471 mg/dL for lay users and 30 to 495 mg/dL for trained operators. Seven altered samples were tested by trained operators only. Linear regression results are presented below:

Linear Regression Analysis:

Lay user vs. YSI $y = 1.00x + 2.7, r = 0.990, n = 146$
Professional vs. YSI $y = 1.03x + 0.7, r = 0.995, n = 153$

The study results met the ISO 15197 accuracy criteria where ninety-five percent (95%) of the individual glucose results fell within ± 15 mg/dL of the YSI results at glucose concentrations < 75 mg/dL and within $\pm 20\%$ at glucose concentrations ≥ 75 mg/dL.

For glucose concentrations <75 mg/dL			
User	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Lay User	11/13 (85%)	12/13 (92%)	13/13 (100%)
Professional	13/16 (81%)	15/16 (94%)	16/16 (100%)

For glucose concentrations >75 mg/dL				
User	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Lay User	72/133 (54%)	120/133 (90%)	130/133 (98%)	131/133 (98%)
Professional	88/137 (64%)	123/137 (90%)	134/137 (98%)	137/137 (100%)

b. *Matrix comparison:*
Not applicable

3. Clinical studies:

a. *Clinical Sensitivity:*
Not applicable

b. *Clinical specificity:*
Not applicable

c. *Other clinical supportive data (when a. and b. are not applicable):*
Not applicable

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range:

The expected glucose range for a non-diabetic, non-pregnant fasting adult is less than 100 mg/dL. Two hours after meals, levels should be less than 140 mg/dL. The healthcare professional determines the range that is appropriate for the patient.

Reference:

American Diabetes Association. Standards of Medical Care in Diabetes—2011. Diabetes Care 2011; 34 (Suppl.1) S11-S61.

N. Instrument Names:

The FreeStyle InsuLinx Blood Glucose Meter,

O. Systems Descriptions:

1. Modes of Operation:

Each test strip is single use and requires a sample volume of 0.3 µl or greater.

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?:

Yes or No

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?:

Yes or No

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes or No

3. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

For single patient home users, the device is intended to be used with capillary whole blood from the fingertip, which is directly applied to the test strip.

5. Calibration:

The FreeStyle InsuLinx meter is programmed with a predetermined calibration slope and intercept of the FreeStyle Lite Blood Glucose Test Strip and therefore does not require user interface coding activities. The FreeStyle InsuLinx meter does not require coding of the device.

6. Quality Control:

The FreeStyle Control Solutions were previously cleared under k013147. There are three levels of Control Solution; Low (40 to 70 mg/dL), Medium (83 to 125 mg/dL) and High (248 to 372 mg/dL). The control ranges are listed on the test strip vial.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

1. A usability study was performed to assess the readability of the labeling by 146 U.S. lay users (aged 19-81 yrs old) who were provided with the test kit containing labeling in English for the US market. Participants varied in age, education, and were evenly divided between men and women. These lay users also completed a questionnaire to indicate whether the device is easy to use and the instructions for use were written in a way that makes it easy to use.

2. Flesch-Kincaid readability assessment was conducted and the results showed that the labeling Owner's Booklet and test strip package insert were written at less than an 8th grade level.
3. A sample volume study was performed to verify the test strip sample volume requirement and the test strip fill error requirement established for the FreeStyle InsuLinx Blood Glucose meter. Whole blood adjusted to three glucose concentrations (48, 105 and 400 mg/dL) were measured with three meters and two test strip lots. Protocols and acceptance criteria were provided and found to be acceptable. Insufficient volume of less than 0.3 μ L will not produce a result.
4. Infection Control studies: The FreeStyle InsuLinx Blood Glucose Monitoring System is intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing facility demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Dispatch Hospital Cleaner Disinfectant Towels with Bleach (EPA Reg. No: 56392-8). Robustness studies were performed by the sponsor demonstrating that there was no change in performance or external materials for the meter and lancing device after 522 cleanings and 522 disinfection steps with Dispatch Hospital Cleaner Disinfectant Towels. The robustness studies were designed to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.
5. The data transmission capability, data transmission port, software and USB connection cable was evaluated in usability study and found to be acceptable. Additionally, verification and validation of these functions were conducted and found to be acceptable.
6. A test certificate for EMC testing and compliance with the relevant regulations was issued by Elliott Laboratories on February 9, 2011.
7. Hematocrit Study: The effect of different hematocrit levels on the accuracy of the device was evaluated on the FreeStyle InsuLinx Blood Glucose Monitoring System with ten meters and three test strip lots. Venous blood samples at seven hematocrit levels (15, 20, 25, 40, 55, 60 and 65%) were adjusted to five concentrations of glucose of 47, 113, 217, 341 and 453 mg/dL. Results of samples at each hematocrit level (N=30) were compared to samples with the same glucose concentration at normal (40%) hematocrit as well as to the corresponding YSI value. All individual results for each meter were within $\pm 15\%$ of the YSI, supporting the claimed hematocrit range of 15 to 65%.
8. Altitude Study: A venous blood sample was adjusted to three different glucose concentrations (48, 105 and 400 mg/dL). Each venous blood sample was tested using ten meters and three lots of test strips. Tests were performed at two elevations (sea level and 10,742 feet). All individual results for each meter were

within $\pm 10\%$ of the YSI, supporting the claimed altitude range of up to 10,000 feet for the glucose meter.

9. The sponsor claims an operating condition range of 4 to 40°C (40 to 104°F) and 5 to 90% relative humidity. Combinations of the claimed temperature and humidity operating conditions were evaluated by measuring whole blood samples at target glucose concentrations of 45, 100, and 400 mg/dL and comparing the meter results to a reference method. The results demonstrated that the system produces accurate results over the claimed range of operating conditions.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.