DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 5, 2016

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

Re: K150332
Trade/Device Name: FreeStyle Lite Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: May 7, 2015
Received: May 8, 2015

Dear Sai Tatavarty:

This letter corrects our substantially equivalent of June 02, 2015.

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,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150332

Device Name
FreeStyle Lite Blood Glucose Monitoring System

Indications for Use *(Describe)*

The FreeStyle Lite 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 in monitoring the effectiveness of a diabetes control program by quantitatively measuring glucose in fresh whole blood from the finger, upper arm and palm. The FreeStyle Lite Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. It is intended to be used by a single person and should not be shared. Alternate site testing should be done only during steady state times (when glucose is not changing rapidly). The FreeStyle Lite Blood Glucose Test Strips are for use with the FreeStyle Lite Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, upper arm and palm.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Abbott Diabetes Care Inc.
1360 South Loop Road,
Alameda, CA 94502

Tel: 510.749.5105
Fax: 510.864.4791
sai.tatavarty@abbott.com

June 4, 2015

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 Tatavarty Tel No. 510-749-5105 Fax No. 510-864-4791 sai.tatavarty@abbott.com
Proprietary Name:	FreeStyle Lite 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 Lite Blood Glucose Test Strips (k092602)
Legal Manufacturer:	Establishment: Abbott Diabetes Care Inc. 1360 South Loop Road Alameda, CA 94502

Indications for use:

The FreeStyle Lite 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 in monitoring the effectiveness of a diabetes control program by quantitatively measuring glucose in fresh whole blood from the finger, upper arm and palm. The FreeStyle Lite Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. It is intended to be used by a single person and should not be shared. Alternate site testing should be done only during steady state times (when glucose is not changing rapidly). The FreeStyle Lite Blood Glucose Test Strips are for use with the FreeStyle Lite Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, upper arm and palm.

Description of the Device:

The FreeStyle Lite Meter, in conjunction with the FreeStyle Lite 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 FreeStyle Lite Meter consists of the following major features:

- Strip Port – where the FreeStyle Lite Test Strip is inserted.
- Buttons – used to turn the meter on/off and recall information stored in the meter.
- Display Window – where test results, messages and information stored in the meter appear.

The device is prepared for use by inserting a glucose test strip in the test strip port. Upon strip insertion, the meter will turn on automatically and perform a display check. The meter will then display the time, month and day (if set). 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, initiated when enough blood has covered the strip electrodes. Following the blood detect, the meter performs the glucose assay measurement.

Principles of Operation:

The FreeStyle Lite Meter (in conjunction with FreeStyle Lite 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 Lite 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 Lite Meter does not require calibration prior to use with the FreeStyle Lite Test Strips. The device is prepared for use by inserting a FreeStyle Lite test strip in the test strip port. Upon strip insertion, the meter will turn on automatically and perform a display check. The meter will then display the time, month and day (if set). 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, initiated 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 incorporate cleaning and disinfection procedures into the FreeStyle Lite System, which may be packaged with the following components and accessories listed below.

- **A.** FreeStyle Lite Meter
- **B.** 10 count vial of FreeStyle Lite Test Strips (may be sold separately)
- **C.** Carrying Case
- **D.** FreeStyle Lancing Device II Lancing Device
- **E.** FreeStyle/Thin Lancets
- **F.** Owner's Booklet
- **G.** Quick Start Guide
- **H.** USB Cable
- **I.** FreeStyle Control Solutions (may be obtained by contacting Customer Service)

Substantial Equivalence:

The FreeStyle Lite Blood Glucose Monitoring System is substantially equivalent to the predicate, which was cleared by the Agency on May 14, 2010, under k092602: FreeStyle Lite Blood Glucose Test Strips. The results obtained from performance studies demonstrate that the FreeStyle Lite Blood Glucose Monitoring System is safe and effective for its intended use and technological characteristics, and therefore, substantially equivalent to the predicate device (k092602).

Comparison to Predicate Device:

The similarities and differences between the FreeStyle Lite Blood Glucose Monitoring System and the predicate (k092602) are highlighted in the table below.

Similarities:

PRODUCT NAME	FreeStyle Lite Blood Glucose Test Strips (K092602)	Modified FreeStyle Lite Blood Glucose Monitoring System (K150332)
CHARACTERISTICS		
Indications for Use	The FreeStyle Lite Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, upper arm and palm, and venous whole blood. The FreeStyle Lite Blood Glucose Monitoring System is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. The FreeStyle Lite Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates or arterial blood.	The FreeStyle Lite 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 in monitoring the effectiveness of a diabetes control program by quantitatively measuring glucose in fresh whole blood from the finger, upper arm and palm. The FreeStyle Lite Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. It is intended to be used by a single person and should not be shared. Alternate site testing should be done only during steady state times (when glucose is not changing rapidly). The FreeStyle Lite Blood Glucose Test Strips are for use with the FreeStyle Lite Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, upper arm and palm.

Classification Product Code	NBW, LFR	Same
Fundamental Technology	The FreeStyle Lite 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
Enzyme	GDH – FAD	Same
Sample Type	Venous or capillary whole blood	Same
AST	Upper arm & palm	Same
Sample Volume	0.3 µL	Same
Measurement Glucose Range	20 to 500 mg/dL	Same
Measurement Time	average 5 seconds	Same
Second sample application	Within 60 seconds	Same
Calibration	None	Same
Lancet	FreeStyle/Thin Lancets	Same
Battery life	500 tests	Same
Hematocrit	15% to 65%	Same
Measurement units	mg/dL	Same
Meter storage temperature	– 4° to 140° F (– 20° to 60° C)	Same
Memory	400 blood glucose and control solution tests with date and time	Same
Operating relative humidity	5% to 90% (non-condensing)	Same
Operating temperature	40° to 104° F (4° to 40° C)	Same
Power Source	One CR 2032, 3V lithium battery, replaceable	Same

Differences:

PRODUCT NAME	FreeStyle Lite Blood Glucose Test Strips (K092602)	Modified FreeStyle Lite Blood Glucose Monitoring System (K150332)
CHARACTERISTICS		
Meter cleaning and disinfection	Clean with: • Mild detergent/soap and water, or • 70% isopropyl alcohol, or • A mixture of 1 part household bleach, 9 parts water	522 cleaning and 522 disinfection cycles (the equivalent of 2 cycles per week for 5 years) with Clorox Healthcare Bleach Germicidal Wipes, EPA Reg. #67619-12
Lancing device cleaning and disinfection	Clean with: • Isopropyl alcohol or • Soap and water or Warm water	210 cleaning and 210 disinfection cycles (the equivalent of 2 cycles per week for 2 years) with Clorox Healthcare Bleach Germicidal Wipes, EPA Reg. #67619-12
Lancing device	FreeStyle Lancing Device	FreeStyle Lancing Device-II