



Food and Drug Administration
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September 30, 2014

ABBOTT DIABETES CARE, INC.
MICHELLE RICAFORT
SENIOR REGULATORY AFFAIRS SPECIALIST
1360 SOUTH LOOP ROAD
ALAMEDA CA 94502

Re: K140371

Trade/Device Name: FreeStyle Precision Neo Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: September 19, 2014
Received: September 22, 2014

Dear Ms. Michelle Ricafort:

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

Indications for Use

510(k) Number (if known)
k140371

Device Name
FreeStyle Precision Neo Blood Glucose Monitoring System

Indications for Use (Describe)

The FreeStyle Precision Neo Blood Glucose Monitoring System is for use outside the body only (in vitro diagnostic use) in the quantitative measurement of glucose in fresh whole blood for self-testing by lay users from the fingers. It is not intended to be used for testing neonatal blood samples or the diagnosis or screening of diabetes.

The FreeStyle Precision Neo System is indicated for home (lay user) in the management of patients with diabetes. It is intended to be used by a single person and should not be shared.

The FreeStyle Precision Neo Blood Glucose Test Strips are for use with the FreeStyle Precision Neo Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

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
Telephone No:	510-749-5400
Fax No:	510-864-4791
Contact Person:	Michelle Ricafort Tel No. 510-749-5250 Fax No. 510-864-4791 michelle.ricafort@abbott.com
Proprietary Name:	FreeStyle Precision Neo 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:	ReliOn Ultima Blood Glucose Monitoring System (k083223)
Legal Manufacturer:	Establishment: Abbott Diabetes Care Ltd. Range Road Witney, Oxon OX29 OYL, UK
U.S. Contact	Establishment: Abbott Diabetes Care Inc. 1360 South Loop Road Alameda, CA 94502

Intended Use:

The FreeStyle Precision Neo Blood Glucose Monitoring System is for use outside the body only (in vitro diagnostic use) in the quantitative measurement of glucose in fresh whole blood for self-testing by lay users from the fingers. It is not intended to be used for testing neonatal blood samples or the diagnosis or screening of diabetes.

The FreeStyle Precision Neo System is indicated for home (lay user) in the management of patients with diabetes. It is intended to be used by a single person and should not be shared.

The FreeStyle Precision Neo Blood Glucose Test Strips are for use with the FreeStyle Precision Neo Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

Description of the Device:

The FreeStyle Precision Neo Meter is for the quantitative measurement of glucose in capillary whole blood samples. The FreeStyle Precision Neo Meter, in conjunction with the FreeStyle Precision Neo Blood Glucose Test Strips, works on the principal of amperometric technology, measuring glucose by its reaction with Glucose Dehydrogenase (GDH) in blood samples or control solutions through electrical mediation.

The FreeStyle Precision Neo System is compatible with the following components and accessories:

- FreeStyle Precision Neo Blood Glucose Test Strips (available separately)
- MediSense Glucose and Ketone Control Solutions (available separately)
- USB Cable (available separately)
- FreeStyle Lancing Device II
- Thin Lancets

Principles of Operation:

The FreeStyle Precision Neo Meter (in conjunction with blood glucose test strips) utilizes amperometric technology to quantitatively measure the glucose concentration in capillary whole blood samples from the fingertip and in MediSense Glucose & Ketone Control Solutions.

The FreeStyle Precision Neo Meter measures glucose electrically. The glucose biosensor is capable of recognising the glucose present in whole blood or control solutions by virtue of the glucose specificity of the enzyme 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 size of the current is directly proportional to the level of the glucose in the applied sample.

The apply blood symbol is displayed for the user to apply blood to the test strip until the meter begins the test. The meter detects trigger current from the test strip when enough blood has covered the strip electrodes and the test countdown will start. When the countdown is complete a test result is displayed on the meter screen. The unit of measure displayed on the meter screen is fixed in mg/dL and cannot be modified by the user.

Substantial Equivalence:

The FreeStyle Precision Neo Blood Glucose Monitoring System is substantially equivalent to the predicate, which was cleared by the Agency on April 16, 2009, to market under k083223: ReliOn Ultima Blood Glucose Monitoring System. The results obtained from performance studies and clinical studies demonstrate that the FreeStyle Precision Neo Blood Glucose Monitoring System is safe and effective for its intended use and technological characteristics, and therefore, substantially equivalent to the predicate device (k083223).

Comparison to Predicate Device:

The similarities and differences between the FreeStyle Precision Neo Blood Glucose Monitoring System and the predicate (k083223) are highlighted in the table below.

	Proposed Device	Predicate Device
PRODUCT NAME	FreeStyle Precision Neo Blood Glucose Monitoring System	ReliOn Ultima Blood Glucose Monitoring System (k083223)
CHARACTERISTICS		
Fundamental Technology	The FreeStyle Precision Neo System, in conjunction with blood glucose test strips, utilizes amperometric technology to quantitatively measure the glucose concentration in whole blood samples.	Same
Principles of Operation	Amperometry	Same
Glucose Operating Range	20-500 mg/dL	Same
Chemistry	GDH-NAD	Same
Glucose Sample volume	0.6 microliters	Same
Glucose Assay Time	5 seconds	Same
Coding (Calibration)	No coding required	Same
Operating Temperature	50° - 122°F	Same
Operating Humidity	10% - 90%, non-condensing	Same
Power Source	CR 2032 lithium (coin cell) batteries	Same
Memory	1,000 events	450 events
Buttons	Touch Press-Button	Keypad
Indications for Use	<p>The FreeStyle Precision Neo Blood Glucose Monitoring System is for use outside the body only (in vitro diagnostic use) in the quantitative measurement of glucose in fresh whole blood for self-testing by lay users from the fingers. It is not intended to be used for testing neonatal blood samples or the diagnosis or screening of diabetes.</p> <p>The FreeStyle Precision Neo System is indicated for home (lay user) in the management of patients with diabetes. It is intended to be used by a</p>	<p>The ReliOn Ultima Blood Glucose Monitoring System is intended for <i>in vitro</i> diagnostic use in the quantitative measurement of glucose in fresh whole blood for self-testing by lay users (e.g., from the finger, forearm, upper arm or base of thumb), or by health care professionals. It is not intended to be used for testing neonatal blood samples.</p> <p>The ReliOn Ultima system is indicated for home (lay user) or professional use in the management of patients with diabetes.</p>

	Proposed Device	Predicate Device
PRODUCT NAME	FreeStyle Precision Neo Blood Glucose Monitoring System	ReliOn Ultima Blood Glucose Monitoring System (k083223)
CHARACTERISTICS		
	<p>single person and should not be shared.</p> <p>The FreeStyle Precision Neo Blood Glucose Test Strips are for use with the FreeStyle Precision Neo Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.</p>	
Product Classification Code	NBW, LFR	NBW, LFR, JJX
Glucose Sample Types	Fresh capillary whole blood from the finger	Finger, forearm, upper arm or base of thumb
Compatible Test Strips	FreeStyle Precision Neo Blood Glucose Test Strips	ReliOn Ultima Blood Glucose Test Strips
Glucose Hematocrit Range	15-65%	30-60%
Altitude	10,000 feet	7,200 feet