DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 27, 2017

ABBOTT DIABETES CARE INC.
STEPHANIE YUN
SR. REGULATORY AFFAIRS SPECIALIST
1360 SOUTH LOOP ROAD
ALAMEDA, CA 94502

Re: K171941
Trade/Device Name: FreeStyle Precision Neo Blood Glucose Test Strips
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW
Dated: August 31, 2017
Received: September 5, 2017

Dear Stephanie Yun:

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,

Kellie B. Kelm -S

for 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)*
K171941

Device Name
FreeStyle Precision Neo Blood Glucose Test Strips

Indications for Use *(Describe)*
The FreeStyle Precision Neo Blood Glucose Test Strips are for use outside the body only (in vitro diagnostic use) with the FreeStyle Libre Reader's built-in meter as components of the FreeStyle Libre Flash Glucose Monitoring System to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. They are not intended to be used for testing neonatal blood samples or for the diagnosis or screening of diabetes.

The FreeStyle Precision Neo Blood Glucose Test Strips are indicated for home (lay) user in the management of patients with diabetes. They are intended to be used by a single person and should not be shared.

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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Abbott
Diabetes Care

k171941

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:	Stephanie Yun Tel No. 510-239-2689 Fax No. 510-864-4791 stephanie.yun@abbott.com
Proprietary Name:	FreeStyle Precision Neo Blood Glucose Test Strips
Common Name:	Glucose Test System
Classification Name:	System, Test, Blood Glucose, Over The Counter, Class II (21 CFR§ 862.1345) Product codes: NBW
Predicate Device:	FreeStyle Precision Neo Blood Glucose Monitoring System (K140371)
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 Test Strips are for use outside the body only (in vitro diagnostic use) with the FreeStyle Libre Reader's built-in meter as components of the FreeStyle Libre Flash Glucose Monitoring System to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. They are not intended to be used for testing neonatal blood samples or for the diagnosis or screening of diabetes.

The FreeStyle Precision Neo Blood Glucose Test Strips are indicated for home (lay) user in the management of patients with diabetes. They are intended to be used by a single person and should not be shared.

Description of the Device:

The FreeStyle Precision Neo Blood Glucose Test Strips are used for the quantitative measurement of glucose in capillary whole blood samples. The FreeStyle Precision Neo Blood Glucose Test Strips, in conjunction with the FreeStyle Libre Reader's built-in meter, 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 Blood Glucose Test Strips are compatible with the FreeStyle Precision Neo Blood Glucose Meter (cleared under k140371) or the FreeStyle Libre Reader's built-in meter.

Principles of Operation:

The FreeStyle Precision Neo Blood Glucose Test Strips (in conjunction with a compatible blood glucose meter) 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 Blood Glucose Test Strips measures glucose electrically when used in conjunction with a compatible blood glucose meter. 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 Test Strips are substantially equivalent to the predicate test strips, which were cleared by the Agency on September 30, 2014, to market under K140371: FreeStyle Precision Neo Blood Glucose: Monitoring System and Test Strips.

The purpose of this submission is to expand the indications for use of the test strips to now include compatibility with the FreeStyle Libre Reader's built-in meter, in addition to the existing FreeStyle Precision Neo Blood Glucose Meter. There is no change to the fundamental technology of the test strip cleared under K140371.

Summary of Clinical and Performance Testing:

Clinical and performance testing was conducted with the FreeStyle Precision Neo Blood Glucose Test Strips and FreeStyle Libre Reader's built-in meter. Performance testing included analysis of precision, linearity and detection limits, interference, environmental conditions, sample volume and infection control studies. A clinical study was performed to assess the device accuracy compared to YSI reference.

Conclusions from Clinical and Performance Evaluations:

The results obtained from clinical and performance studies show that all performance characteristics were met. The results demonstrate that the FreeStyle Precision Neo Blood Glucose Test Strips are safe and effective for its intended use and technological characteristics when used with the FreeStyle Libre Reader's built-in meter, and therefore, substantially equivalent to the predicate device (K140371).

Comparison to Predicate Device:

The similarities and differences between the FreeStyle Precision Neo Blood Glucose Test Strips and the predicate test strips (K140371) are highlighted in Tables 1 and 2 below.

Table 1: Similarities between the Proposed and Predicate Device

	Proposed Device	**Predicate Device**
PRODUCT NAME	**FreeStyle Precision Neo Blood Glucose Test Strips**	**FreeStyle Precision Neo Blood Glucose Monitoring System(K140371)**
CHARACTERISTICS		
Fundamental Technology	The FreeStyle Precision Neo Blood Glucose Test Strips, in conjunction with blood glucose meter, 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
Sample Application	Top or end fill	Same
Operating Temperature	59° - 104°F	Same
Operating Humidity	10% - 90%, non-condensing	Same
Product Classification Code	NBW	NBW, LFR
Glucose Sample Types	Fresh capillary whole blood from the finger	Same
Glucose Hematocrit Range	15-65%	Same
Altitude	10,000 feet	Same

Table 2: Differences between the Proposed and Predicate Device

	Proposed Device	**Predicate Device**
PRODUCT NAME	**FreeStyle Precision Neo Blood Glucose Test Strips**	**FreeStyle Precision Neo Blood Glucose Monitoring System(K140371)**
CHARACTERISTICS		
Indications for Use (for Test Strip)	The FreeStyle Precision Neo Blood Glucose Test Strips are for use outside the body only (in vitro diagnostic use) with the FreeStyle Libre Reader's built-in meter as components of the FreeStyle Libre Flash Glucose Monitoring System to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. They are not intended to be used for testing neonatal blood samples or for the diagnosis or screening of diabetes. The FreeStyle Precision Neo Blood Glucose Test Strips are indicated for home (lay) user in the management of patients with diabetes. They are intended to be used by a single person and should not be shared.	The FreeStyle Precision Neo Blood Glucose Test Strips are for use outside the body only (in vitro diagnostic use) with the FreeStyle Precision Neo Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. They are not intended to be used for testing neonatal blood samples or for the diagnosis or screening of diabetes. The FreeStyle Precision Neo Blood Glucose Test Strips are indicated for home (lay) user in the management of patients with diabetes. They are intended to be used by a single person and should not be shared.