DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 19, 2016

ABBOTT DIABETES CARE INC.
ARUL STERLIN
ASSOCIATE DIRECTOR, REGULATORY AFFAIRS
1360 SOUTH LOOP ROAD
ALAMEDA CA 94202

Re: K153330
Trade/Device Name: FreeStyle Precision Neo H Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: November 23, 2015
Received: November 24, 2015

Dear Arul Sterlin:

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, 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)*
k153330

Device Name
FreeStyle Precision Neo H Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Freestyle Precision Neo H Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger, and in venous and arterial whole blood.

The Freestyle Precision Neo H Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use). It is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single-use, auto-disabling lancing devices.

The system should not be used for the diagnosis of or screening for diabetes or for neonatal testing.

The Freestyle Precision Neo H Blood Glucose Test Strips are for use with the Freestyle Precision Neo H Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood from the finger, and from venous and arterial whole blood.

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
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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."*

## 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.

| | |
|---|---|
| Date Prepared: | February 17, 2016 |
| 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: | Arul Sterlin<br>Tel No. 510-864-4310<br>Fax No. 510-864-4791<br>arul.sterlin@abbott.com |
| Proprietary Name: | FreeStyle Precision Neo H Blood Glucose Monitoring System |
| Common Name: | Glucose Test System |
| Classification Name: | Glucose Dehydrogenase, Glucose, Class II (21 CFR§ 862.1345)<br>Product codes: NBW, LFR |
| Predicate Device: | FreeStyle Precision Pro Blood Glucose and Beta-Ketone Monitoring System (k132511) |
| Legal Manufacturer: | Establishment:<br>Abbott Diabetes Care Ltd.<br>Range Road<br>Witney, Oxon<br>OX29 OYL, UK |
| U.S. Contact | Establishment:<br>Abbott Diabetes Care Inc.<br>1360 South Loop Road<br>Alameda, CA 94502 |

**Intended Use:**

The Freestyle Precision Neo H Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger, and in venous and arterial whole blood.

The Freestyle Precision Neo H Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use). It is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single-use, auto-disabling lancing devices.

The system should not be used for the diagnosis of or screening for diabetes or for neonatal testing.

The Freestyle Precision Neo H Blood Glucose Test Strips are for use with the Freestyle Precision Neo H Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood from the finger, and from venous and arterial whole blood.

**Description of the Device:**

The FreeStyle Precision Neo H meter provides the following features:

- Quantitative measurement of glucose in capillary, venous and arterial whole blood samples
- Quality Control Reminder
- Out-of-Range Indicators

The FreeStyle Precision Neo H Meter is for use by healthcare professionals (HCPs) for multiple-patient use. The FreeStyle Precision Neo H Meter, in conjunction with the FreeStyle Precision Neo H 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 H System is compatible with the following components and accessories:

- FreeStyle Precision Neo H Blood Glucose Test Strips
- MediSense Glucose and Ketone Control Solutions
- FreeStyle Auto-Assist Neo Data Management System
- USB Cable

**Principles of Operation:**

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

The FreeStyle Precision Neo H Meter measures glucose electrically. 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 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 H Blood Glucose Monitoring System is substantially equivalent to the predicate, which was cleared by the Agency on December 24, 2013, to market under k132511: FreeStyle Precision Pro Blood Glucose and β-Ketone Monitoring System. The results obtained from performance studies and clinical studies demonstrate that the FreeStyle Precision Neo H Blood Glucose Monitoring System is safe and effective for its intended use and technological characteristics, and therefore, substantially equivalent to the predicate device (k132511).

**Comparison to Predicate Device:**

The similarities and differences between the FreeStyle Precision Neo H Blood Glucose Monitoring System and the predicate (k132511) are highlighted in the table below.

| | Proposed Device | Predicate Device |
|---|---|---|
| **PRODUCT NAME** | **FreeStyle Precision Neo H Blood Glucose Monitoring System (k153330)** | **FreeStyle Precision Pro Blood Glucose and Beta-Ketone Monitoring System (k132511)** |
| **CHARACTERISTICS** | | |
| Fundamental Technology | The FreeStyle Precision Neo H System (in conjunction with blood glucose test strips) utilizes amperometric technology to quantitatively measure the glucose concentration in whole blood samples. | Same |
| Glucose Hematocrit Range | 15-65% | Same |
| Glucose Operating Range | 20-500 mg/dL | Same |
| Use Life | 3 years | Same |
| Cleaning and Disinfection Cycles | 10,950 cycles validated | Same |
| Operating Humidity | 10-90% | Same |
| Glucose Sample volume | 0.6 microliters | Same |
| Glucose Hematocrit Compensation | Yes | Same |
| Glucose Assay Time | 5 seconds | Same |
| Operating Temperature | 59° to 104°F | Same |

| | Proposed Device | Predicate Device |
|---|---|---|
| **PRODUCT NAME** | **FreeStyle Precision Neo H Blood Glucose Monitoring System (k153330)** | **FreeStyle Precision Pro Blood Glucose and Beta-Ketone Monitoring System (k132511)** |
| **CHARACTERISTICS** | | |
| Indications for Use | The Freestyle Precision Neo H Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger, and in venous and arterial whole blood when used within 30 minutes after collection.<br><br>The Freestyle Precision Neo H Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use). It is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single-use, auto-disabling lancing devices.<br><br>The system should not be used for the diagnosis of or screening for diabetes. | The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger, and from venous, arterial and neonatal whole blood, and for the quantitative measurement of β- ketone (beta-hydroxybutyrate) in flesh capillary whole blood from the finger and venous, arterial, and neonatal whole blood when used within 30 minutes after collection.<br><br>The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single use, auto-disabling lancing devices.<br><br>The system should not be used for the diagnosis of or screening for diabetes.<br><br>The Freestyle Precision Pro Blood Glucose Test Strips are for use with the Freestyle Precision |

| | Proposed Device | Predicate Device |
|---|---|---|
| **PRODUCT NAME** | **FreeStyle Precision Neo H Blood Glucose Monitoring System (k153330)** | **FreeStyle Precision Pro Blood Glucose and Beta-Ketone Monitoring System (k132511)** |
| **CHARACTERISTICS** | | |
| | The Freestyle Precision Neo H Blood Glucose Test Strips are for use with the Freestyle Precision Neo H Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood sample drawn from the fingertips, and from venous and arterial whole blood. | Pro Blood Glucose and β-Ketone Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips and from venous, arterial. and neonatal whole blood. The Freestyle Precision Pro Blood β-Ketone Test Strips are for use with the Freestyle Precision Pro Blood Glucose and P-Ketone Meter to quantitatively measure β-ketone in fresh capillary whole blood samples drawn from the fingertips and from venous, arterial, and neonatal whole blood.<br><br>Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System enables automatic transmission of stored data to a data management system using the docking station (optional), a data upload cable (optional), or wirelessly (optional) in a WiFi enabled facility when the meter and data management systems are properly configured. |
| Product Classification Code | NBW, LFR | NBW, JIN, JQP, LFR |
| Glucose Sample Types | Fresh capillary whole blood from the finger, venous and arterial whole blood samples | Fresh capillary whole blood from the finger, venous, arterial, and neonatal whole blood samples |
| Calibration | ROM | Barcode scanner |
| Altitude | 10,000 feet above sea level | 7,200 feet above sea level |
| Data Management System | FreeStyle Auto Assist Neo Data Management System | Precision Web Point-of-Care Health Management System |
| Data Upload | USB Data Cable | USB Data Cable, Docking Station or Wireless |

| | Proposed Device | Predicate Device |
|---|---|---|
| **PRODUCT NAME** | **FreeStyle Precision Neo H Blood Glucose Monitoring System (k153330)** | **FreeStyle Precision Pro Blood Glucose and Beta-Ketone Monitoring System (k132511)** |
| **CHARACTERISTICS** | | |
| Compatible Test Strips | FreeStyle Precision Neo H Blood Glucose Test Strips | FreeStyle Precision Pro Blood Glucose Test Strips and FreeStyle Precision Pro Blood β-Ketone Test Strips |