



SD BIOSENSOR
C/O PRISCILLA CHUNG
REGULATORY AFFAIRS CONSULTANT
2651 E CHAPMAN AVE STE 110
FULLERTON CA 92831

January 14, 2016

Re: K151265

Trade/Device Name: SD GlucoNFC Blood Glucose Monitoring System,
SD GlucoNFC Multi Blood Glucose Monitoring System

Regulation Number: 21 CFR 862.1345

Regulation Name: Glucose test system

Regulatory Class: II

Product Code: NBW, LFR, JJX

Dated: October 5, 2015

Received: October 09, 2015

Dear Priscilla Chung:

This letter corrects our substantially equivalent letter of November 24, 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,


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

Indications for Use

510(k) Number (if known)
K151265

Device Name

SD GlucoNFC Blood Glucose Monitoring System

Indications for Use (Describe)

SD GlucoNFC Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, forearm or upper arm. SD GlucoNFC Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It 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 SD GlucoNFC Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The SD GlucoNFC Blood Glucose Monitoring System is not for use in neonates. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

SD GlucoNFC Blood Glucose Test Strips are for use with SD GlucoNFC Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm or upper arm.

SD GlucoNavii® Control Solution is intended for Quality Control of the SD GlucoNFC Blood Glucose Monitoring System. The control solution helps to check that the meter and test strips are working together properly and that the test is performing correctly.

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
PRASStaff@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."

Indications for Use

510(k) Number (if known)
K151265

Device Name

SD GlucoNFC Multi Blood Glucose Monitoring System

Indications for Use (Describe)

SD GlucoNFC Multi Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, forearm or upper arm and venous whole blood. The SD GlucoNFC Multi Blood Glucose 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 diabetes control program. This system should only be used with auto-disabling, single-use lancing devices.

The SD GlucoNFC Multi Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The SD GlucoNFC Multi Blood Glucose Monitoring System is not for use in neonates Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

SD GlucoNFC Multi Blood Glucose Test Strips are for use with SD GlucoNFC Multi Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm or upper arm and venous whole blood.

SD GlucoNavii® Control Solution is intended for Quality Control of the SD GlucoNFC Multi Blood Glucose Monitoring System. The control solution helps to check that the meter and test strips are working together properly and that the test is performing correctly.

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)

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510(k) Summary (K151265)

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is:

Date of Summary: November 20, 2015

1. SUBMITTER'S IDENTIFICATION:

Manufacturer

SD Biosensor, Inc.
C-4th&5th, 16, Deogyong-Daero, 1556beon-Gil, Yeongtong-Gu,
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Contact Person

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Official Correspondent (U.S. Designated Agent) / Priscilla Chung (Regulatory Consultant)
SD Biosensor, Inc.
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TEL: (714) 202-5789
FAX: (714) 409-3357
E-MAIL: juhee.c@lkconsultinggroup.com

2. DEVICE NAME:

Proprietary Name:	SD GlucoNFC Blood Glucose Monitoring System SD GlucoNFC Multi Blood Glucose Monitoring System
Common Name:	Blood Glucose Monitoring System
Regulation Number:	21 CFR §862.1345, 21 CFR §862.1660
Classification Name:	Blood Glucose Test System
Product Code:	NBW
Subsequent Product Code:	LFR / JJX
Regulatory Class:	Class II Class I reserved

3. PREDICATE DEVICES:

SD GlucoMentor™ BGMS (K123517) by SD BIOSENSOR.
SD GlucoMentor™ Multi BGMS (K123517) by SD BIOSENSOR

4. DEVICE DESCRIPTION:

SD GlucoNFC Blood Glucose Monitoring System and GlucoNFC Multi Blood Glucose Monitoring Systems are OTC/ Rx blood glucose monitoring systems. The SD GlucoNFC Blood Glucose Monitoring System is indicated for single-patient use at home (over-the-counter; OTC) and should not be shared, while the SD GlucoNFC Multi Blood Glucose Monitoring System is for multi-patient use in a professional healthcare setting (prescription; POC), in order to help monitor the effectiveness of diabetes control. The devices contain near field communication (NFC) technology.

SD GlucoNFC Blood Glucose Monitoring System includes:

- SD GlucoNFC Blood Glucose Meter
- SD GlucoNFC Blood Glucose Test Strips
- SD Glucose Check Strip
- SD GlucoNavii® Control Solution – Level 2
- Lancet
- Lancing device (with a white cap for fingertip testing and a clear cap for Alternative Site Testing)
- User Instruction Guide
- Test Strip Package Insert
- Control Solution Package Insert

SD GlucoNFC Multi Blood Glucose Monitoring System includes

- SD GlucoNFC Multi Blood Glucose Meter
- SD GlucoNFC Multi Blood Glucose Test Strips
- SD Glucose Check Strip
- SD GlucoNavii® Control Solution – Level 2
- User Instruction Guide
- Test Strip Package Insert
- Control Solution Package Insert

A drop of blood sample works with Glucose dehydrogenase (GDH) and potassium ferrocyanide in the test strip to make a small electric current proportional to the glucose concentration in the blood. The meter reads the current and displays the blood glucose result equivalent to the current.

The user can search the stored results with three presentations of 7, 14 and 30-day averages of test results stored in memory: non-meal, pre-meal and post-meal state averages. The system can set the beep, hypo warning, date, time, post-meal alarm and alarm. The system can also set the pre-meal and post-meal mark. Test results are displayed with mg/dL units. A check strip allows the meter to check a problem and the control solution allows the meter and test strip to be checked.

5. INDICATION FOR USE:

SD GlucoNFC Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, forearm or upper arm. SD GlucoNFC Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It 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 SD GlucoNFC Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The SD GlucoNFC Blood Glucose Monitoring System is not for use in neonates. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

SD GlucoNFC Blood Glucose Test Strips are for use with SD GlucoNFC Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm or upper arm.

SD GlucoNavii® Control Solution is intended for Quality Control of the SD GlucoNFC Blood Glucose Monitoring System. The control solution helps to check that the meter and test strips are working together properly and that the test is performing correctly.

SD GlucoNFC Multi Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, forearm or upper arm and venous whole blood. The SD GlucoNFC Multi Blood Glucose 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 diabetes control program. This system should only be used with auto-disabling, single-use lancing devices.

The SD GlucoNFC Multi Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The SD GlucoNFC Multi Blood Glucose Monitoring System is not for use in neonates. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

SD GlucoNFC Multi Blood Glucose Test Strips are for use with SD GlucoNFC Multi Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm or upper arm and venous whole blood.

SD GlucoNavii® Control Solution is intended for Quality Control of the SD GlucoNFC Multi Blood Glucose Monitoring System. The control solution helps to check that the meter and test strips are working together properly and that the test is performing correctly.

6. COMPARISON TO PREDICATE DEVICE:

The SD GlucoNFC and GlucoNFC Multi Blood Glucose Monitoring Systems are substantially equivalent to our SD GlucoMentor™ and SD GlucoMentor™ Multi, K123517. Both the subject and predicate devices are similar in intended use and basic fundamental scientific technology. Please refer to the following similarities and difference comparison chart:

Similarities and Differences					
Item	Subject Device K151265 SD GlucoNFC Blood Glucose Monitoring System	Subject Device K151265 SD GlucoNFC Multi Blood Glucose Monitoring System	Predicate Device K123517 SD GlucoMentor™ BGMS	Predicate Device K123517 SD GlucoMentor™ Multi BGMS	Discussion of Differences
Indications for Use	<i>OTC setting: For Single-User, In-Vitro Diagnostic Use Only by Patient (at-home) with Diabetes</i>	<i>POC setting: For Multi-User, In-Vitro Diagnostic Use Only by Healthcare Professionals at Professional Clinic</i>	<i>OTC setting: For Single-User, In-Vitro Diagnostic Use Only by Patient (at-home) with Diabetes</i>	<i>POC setting: For Multi-User, In-Vitro Diagnostic Use Only by Healthcare Professionals at Professional Clinic</i>	same
Test Time	5 seconds		5 seconds		
Measuring Range	20-600 mg/dL		20-600 mg/dL		same
Operating Temperature	<i>46-113°F (8-45°C) for blood sample 64-86°F(18-30°C) for control solution</i>		<i>50-113°F (10-45°C) for blood sample 64-86°F (18-30°C) for control solution</i>		different
Operating Humidity	10-90% RH		15-95% RH		equivalent
Operating Altitude	up to 11,548ft.		up to 11,351ft.		different
Hematocrit	10-70%		20-60%		different
Memory Capacity	300 test results		500 test results		equivalent
Coding	N/A		N/A		same
Meter Dimensions	48mm × 90 mm × 15 mm		47mm x 95mm x 17.5mm		different
Meter Weight	50g with battery		47.5g with battery		different
Unit of measure	mg/dL				same
Sample type	<i>Fresh capillary whole blood</i>	<i>Fresh capillary whole blood and venous whole blood</i>	<i>Fresh capillary whole blood</i>		different
Sample sites	<i>Fingertip, palm, forearm or upper arm</i>				same
Sample volume	0.5 µL		0.3 µL		equivalent
Monitor	LCD display				same
Backlight	No				same
Power Supply	3V CR2032 Battery x1 (Replaceable)				same
Power Saving	<i>Automatic shut off after 1 minute of inactivity WITHOUT inserting test strip Automatic shut off after 3 minutes of inactivity WITH test strip inserted</i>				same

Similarities and Differences					
Item	Subject Device K151265 SD GlucoNFC Blood Glucose Monitoring System	Subject Device K151265 SD GlucoNFC Multi Blood Glucose Monitoring System	Predicate Device K123517 SD GlucoMentor™ BGMS	Predicate Device K123517 SD GlucoMentor™ Multi BGMS	Discussion of Differences
Battery Life	<i>Approximately 1,000 Tests</i>				<i>same</i>
Test Strip Technology	<i>Glucose Dehydrogenase (GDH)</i>		<i>Glucose Oxidase (GOD)</i>		<i>different</i>
Test Principle	<i>Electrochemical biosensor</i>				<i>same</i>
Sample Application	<i>Test strip capillary draw</i>				<i>same</i>
Calibration	<i>Plasma-calibrated</i>				<i>same</i>
Test Strip Storage Conditions	<i>Temperature 2-32°C(36-90°F)</i>				<i>same</i>
PC link Feature	<i>Yes, USB Cable or NFC Reader/Writer</i>		<i>Yes, USB Cable</i>		<i>equivalent</i>
Smart device link Feature	<i>Yes</i>		<i>No</i>		<i>different</i>

There are a number of differences between the subject devices and the predicate devices as presented in the table above, however, the non-clinical studies and clinical-studies provided in this submission demonstrated that the differences do not raise a question of safety and effectiveness. Based on the information provided, we conclude that the subject device is substantially equivalent to the predicate device.

7. DISCUSSION OF NON-CLINICAL and CLINICAL TESTS PERFORMED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE ARE AS FOLLOWS:

The following testing was conducted on our subject device:

- Software Validation
- Electrical Safety (IEC 61010-1:2001& IEC 61010-2-101:2002)
- Electromagnetic Compatibility (IEC 60601-1-2)
- Radio Frequency (FCC Part 15.101)
- System Accuracy
- Precision
- Linearity
- Sample Volume
- Hematocrit
- Matrix comparison
- Interference Substances
- Operating Condition (Temperature and Humidity)
- High Altitude
- Disinfection / Virucidal Efficacy Validation and robustness study
- Stability for Test Strip and Control Solution
- Readability for proposed labeling
- Data accuracy & wireless coexistence
- Memory data rollover
- Vibration

All the test results met the pre-set criteria and supported that the subject device is substantially equivalent to the predicate devices in the market.

8. CONCLUSION:

Based on documentation supplied with this submission, conclusions drawn from clinical and bench testing of the subject device demonstrates that the subject devices are substantially equivalent to our legally marketed predicate devices.