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

August 5, 2015

SD BIOSENSOR, INC.
C/O PRISCILLA CHUNG
2651 E CHAPMAN AVE STE 110
FULLERTON CA 92831

Re: K132929
Trade/Device Name: SD GlucoNavii® Mentor NFC Multi Blood Glucose Monitoring System,
SD GlucoNavii® Mentor NFC Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW
Dated: July 24, 2015
Received: July 30, 2015

Dear Priscilla Chung:

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)*
k132929

Device Name
SD GlucoNavii® Mentor NFC Blood Glucose Monitoring System

Indications for Use *(Describe)*
SD GlucoNavii® Mentor NFC Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, upper arm, or forearm. SD GlucoNavii® Mentor NFC 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 GlucoNavii® Mentor NFC Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The SD GlucoNavii® Mentor NFC 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 GlucoNavii® Mentor NFC Blood Glucose Monitoring System is intended to be used to transmit glucose values to compatible mobile application or PC software through use of radio frequency communication.

SD GlucoNavii® Mentor NFC Blood Glucose Test Strips are for use with SD GlucoNavii® Mentor NFC Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, or 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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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)*
k132929

Device Name
SD GlucoNavii® Mentor NFC Multi Blood Glucose Monitoring System

Indications for Use *(Describe)*
SD GlucoNavii® Mentor NFC 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, upper arm, or forearm. The SD GlucoNavii® Mentor NFC 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 GlucoNavii® Mentor NFC Multi Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The SD GlucoNavii® Mentor NFC 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 GlucoNavii® Mentor NFC Multi Blood Glucose Monitoring System is intended to be used to transmit glucose values to compatible mobile application or PC software through use of radio frequency communication.

SD GlucoNavii® Mentor NFC Multi Blood Glucose Test Strips are for use with SD GlucoNavii® Mentor NFC Multi Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, or 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

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

The assigned 510(k) number: k132929

Date of Summary: August 4, 2015

1. SUBMITTER'S IDENTIFICATION:

Manufacturer

SD Biosensor, Inc.
C-4th&5th, 16, Deogyeong-Daero,1556beon-Gil, Yeongtong-Gu,
Suwon-si, Gyeonggi-Do, KOREA, REPUBLIC OF 443-813
TEL: 82-31-300-0418
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Contact Person

Ms. Yeon Park / Regulatory
Email: py@sdbiosensor.com
Official Correspondent (U.S. designated agent) Priscilla Chung (Regulatory Consultant)
SD Biosensor, Inc.
c/o LK Consulting Group USA, Inc.
2651 E Chapman Ave Ste 110, Fullerton CA 92831
TEL: (714) 202-5789
FAX: (714) 409-3357
E-MAIL: juhee.c@lkconsultinggroup.com

2. DEVICE NAME:

Proprietary Name:	SD GlucoNavii® Mentor NFC SD GlucoNavii® Mentor NFC Multi
Common Name:	Blood Glucose Monitoring System
Regulation Number:	21 CFR §862.1345
Classification Name:	Blood Glucose Test System
Product Code:	NBW
Subsequent Product Code:	CGA / JJX
Regulatory Class:	II

3. PREDICATE DEVICES:

SmartLink™ GOLD Blood Glucose Monitoring System (K100398) by STANDARD DIAGNOSTICS, INC.

4. DEVICEDESCRIPTION:

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

SD GlucoNavii® Mentor NFC Blood Glucose Monitoring System includes:

- SD GlucoNavii® Mentor NFC Blood Glucose Meter
- SD GlucoNavii® Mentor NFC Blood Glucose Test Strips
- SD Glucose Check Strip
- SD Glucose Control Solution – Level M
- 3V Battery Type CR2032
- User Instruction Guide
- Quick Guide
- Test Strip Package Insert
- Control Solution Package Insert
- Carrying Case
- Lancing Device, Lancet

SD GlucoNavii® Mentor NFC Multi Blood Glucose Monitoring System includes:

- SD GlucoNavii® Mentor NFC Multi Blood Glucose Meter
- SD GlucoNavii® Mentor NFC Multi Blood Glucose Test Strips
- SD Glucose Check Strip
- SD Glucose Control Solution – Level M
- 3V Battery Type CR2032
- User Instruction Guide
- Quick Guide
- Test Strip Package Insert
- Control Solution Package Insert
- Carrying Case

Optional software accessory

- GlucoNavii® DMS
- GlucoNavii®

A drop of blood sample from the finger prick works with glucose oxidase and the mediators 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: normal, 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 unit. 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 GlucoNavii® Mentor NFC Blood Glucose Monitoring System

SD GlucoNavii® Mentor NFC Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, upper arm, or forearm. SD GlucoNavii® Mentor NFC 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 GlucoNavii® Mentor NFC Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The SD GlucoNavii® Mentor NFC 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 GlucoNavii® Mentor NFC Blood Glucose Monitoring System is intended to be used to transmit glucose values to compatible mobile application or PC software through use of radio frequency communication.

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

SD GlucoNavii® Mentor NFC Multi Blood Glucose Monitoring System

SD GlucoNavii® Mentor NFC 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, upper arm, or forearm. The SD GlucoNavii® Mentor NFC 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 GlucoNavii® Mentor NFC Multi Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The SD GlucoNavii® Mentor NFC 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 GlucoNavii® Mentor NFC Multi Blood Glucose Monitoring System is intended to be used to transmit glucose values to compatible mobile application or PC software through use of radio frequency communication.

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

6. COMPARISION TO PREDICATE DEVICE:

The SD GlucoNavii® Mentor NFC and NFC Multi Blood Glucose Monitoring Systems are substantially equivalent to our SD SmartLink™ GOLD Blood Glucose Monitoring System, K100398. Both the subject and predicate devices are similar in intended use and basic fundamental scientific technology.

Please refer to the following similarities and differences comparison chart:

Item	**Subject Device** SD GlucoNavii® Mentor NFC Blood Glucose Monitoring System	**Subject Device** SD GlucoNavii® Mentor NFC **Multi** Blood Glucose Monitoring System	**Predicate Device** K100398 SmartLink™ GOLD BGMS
Appearance			
Indications for Use	***OTC setting***: *For Single-User, In-Vitro Diagnostic Use Only by Patient (at-home) with Diabetes*	***OTC setting***: *For Single-User, In-Vitro Diagnostic Use Only by Patient (at-home) with Diabetes* ***POC setting***: *For Multi-User, In-Vitro Diagnostic Use Only by Healthcare Professionals at Professional Clinic*	***OTC setting***: *For Single-User, In-Vitro Diagnostic Use Only by Patient (at-home) with Diabetes* ***POC setting***: *For Multi-User, In-Vitro Diagnostic Use Only by Healthcare Professionals at Professional Clinic*
Test Time	5 seconds		
Measuring Range	20-600 mg/dL		
Operating Temperature	10-32℃ (50-90℉) for Test Strip / 18-30℃ (64.4-86℉) for Control Solution		
Operating Humidity	15-95% RH		
Operating Altitude	up to 11,351 feet		
Hematocrit	20-60%		
Memory Capacity	*300 test results*		*400 test results*

Coding	N/A	
Meter Dimensions	*50mm x 93mm x 18mm*	*47mm x 95mm x 17.5 mm*
Meter Weight	*50g with battery*	*47.5 with battery*
Unit of measure	mg/dL / mmol/L	
Sample type	Fresh capillary whole blood	
Sample sites	Fingertip, palm, forearm or upper arm	
Sample volume	*0.3 µL*	*0.9 µL*
Monitor	LCD display	
Backlight	No	
Power Supply	3V CR2032 Battery x1(Replaceable)	
Power Saving	• Automatic shut off after **1 minute** of inactivity WITHOUT inserting test strip • Automatic shut off after **3 minutes** of inactivity WITH test strip inserted	
Battery Life	Approximately 1,000 Tests	
Test Strip Technology	Glucose Oxidase (GOD)	
Test Principle	Electrochemical biosensor	
Sample Application	Test strip capillary draw	
Calibration	Plasma-calibrated	
Test Strip Storage Temperature	2-32℃ (36-90℉)	
Test Strip Storage Humidity	*10-95%RH*	*N/A*
Control Solution	2 Levels Middle: 90-140 mg/dL High: 170-240 mg/dL	
PC link Feature	*Yes, USB Cable or NFC Reader/Writer*	*Yes, USB Cable*
Smart device link Feature	*Yes*	*No*

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

Based on our risk analysis evaluation results, and, in accordance with the FDA "Draft Guidance for Industry and FDA Staff – Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems, 10/24/06", outlined performance characteristics, the following testing was conducted to support the modifications found in our subject device:

- Software Validation
- Electrical Safety (IEC 61010-1:2001& IEC 61010-2-101:2002)
- Electromagnetic Compatibility (IEC 60601-1-2:2007)
- Radio Frequency (FCC Part 15.255 Subpart C)
- System Accuracy
- Precision
- Linearity
- Sample Volume
- Hematocrit
- Interference Substances
- Operating Condition (Temperature and Humidity)
- High Altitude
- Disinfection / Virucidal Efficacy Validation
- Stability for Test Strip and Control Solution
- Readability for proposed labeling

None of the testing demonstrated any design characteristics that violated the requirements of the FDA recognized standards or resulted in any safety hazards. It was our conclusion that testing met all relevant standards requirements.

The study results support that SD GlucoNavii® Mentor NFC and NFC Multi Blood Glucose Monitoring Systems are substantially equivalence to other predicate devices in the market.

8. DISCUSSION OF CLINICAL TESTS PERFORMED:

Clinical sensitivity and clinical specificity testing are not applicable.

System accuracy evaluations (Method Comparison with Predicate Device) for the SD GlucoNavii® Mentor NFC and NFC Multi Blood Glucose Monitoring Systems were performed according to ISO 15197.

User performance studies were performed to demonstrate that lay consumers could obtain accurate results using the SD GlucoNavii® Mentor NFC and NFC Multi Blood Glucose Monitoring Systems. The studies were performed using capillary whole blood from fingertip, palm, forearm, and upper arm sample sites.

9. CONCLUSION:

Based on documentation supplied with this submission, conclusions drawn from clinical and bench testing of the subject device demonstrates that the subject devices SD GlucoNavii® Mentor NFC and NFC Multi Blood Glucose Monitoring Systems are substantially equivalent to our legally marketed predicate devices.