



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

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

June 24, 2016

Re: K153201

Trade/Device Name: SD GlucoNavii® Mentor BT Blood Glucose Monitoring System,  
SD GlucoNavii® Mentor BT Multi Blood Glucose Monitoring System  
Regulation Number: 21 CFR 862.1345  
Regulation Name: Glucose test system  
Regulatory Class: II  
Product Code: NBW, CGA  
Dated: May 23, 2016  
Received: May 26, 2016

Dear Ms. 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,

**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)

K153201

Device Name

SD GlucoNavii® Mentor BT Blood Glucose Monitoring System

Indications for Use (Describe)

SD GlucoNavii® Mentor BT 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 BT 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 BT Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The SD GlucoNavii® Mentor BT 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 BT Blood Glucose Test Strips are for use with SD GlucoNavii® Mentor BT 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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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## Indications for Use

510(k) Number (if known)  
K153201

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

### Indications for Use (Describe)

SD GlucoNavii® Mentor BT 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 BT 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 BT Multi Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The SD GlucoNavii® Mentor BT 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 BT Multi Blood Glucose Test Strips are for use with SD GlucoNavii® Mentor BT 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)

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## 510(k) Summary

### (k153201)

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

**Date of Summary:** June 22, 2016

#### **1. SUBMITTER'S IDENTIFICATION:**

##### **Manufacturer**

SD Biosensor, Inc.

C-4th&5th, 16, Deogyong-Daero, 1556beon-Gil, Yeongtong-Gu,

Suwon-si, Gyeonggi-Do, KOREA, REPUBLIC OF 443-813

TEL: 82-31-300-0423

FAX: 82-31-300-0497

##### **Contact Person**

SunYoung Jeong

Email: syj@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:**

<b>Proprietary Name:</b>	SD GlucoNavii® Mentor BT Blood Glucose Monitoring System SD GlucoNavii® Mentor BT Multi Blood Glucose Monitoring System
<b>Common Name:</b>	Blood Glucose Monitoring System
<b>Regulation Number:</b>	21 CFR §862.1345
<b>Classification Name:</b>	Blood Glucose Test System
<b>Product Code:</b>	NBW
<b>SubsequentProduct Code:</b>	CGA
<b>Regulatory Class:</b>	II

### **3. PREDICATE DEVICES:**

SD GlucoNavii® Mentor NFC Blood Glucose Monitoring System and SD GlucoNavii® Mentor NFC Multi Blood Glucose Monitoring System (K132929) by SD Biosensor, Inc.

### **4. DEVICEDescription:**

SD GlucoNavii® Mentor BT and BT Multi Blood Glucose Monitoring Systems are OTC/ Rx blood glucose monitoring systems. The SD GlucoNavii® Mentor BT 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 BT 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.

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.

A Bluetooth unit for data transfer has been added to the subject devices in addition to NFC and USB cable communication features.

The following modifications were made on the subject device from the predicate device (K132929).

- 1) The addition of Bluetooth for wireless transmission of data to mobile device or PC, and which comprises the following modifications:
  - i. Changed printed circuit board (PCB) layout.
  - ii. Added Bluetooth module to PCB.
  - iii. Added and deleted electronic components to support the Bluetooth Module.
  - iv. Deleted USB communication circuit.
  - v. Changed Firmware.
  - vi. Added Bluetooth icon to display.
  - vii. Extended automatic meter shutoff times to allow enough time for data transfer via Bluetooth.
- 2) Memory capacity for stored glucose test results decreased from 300 to 100 records.
- 3) The trade name of the systems has changed from SD GlucoNavii® Mentor NFC Blood Glucose Monitoring System and SD GlucoNavii® Mentor NFC Multi Blood Glucose Monitoring System to SD GlucoNavii® Mentor BT Blood Glucose Monitoring System and SD GlucoNavii® Mentor BT Multi Blood Glucose Monitoring System.

- 4) The trade name of the test strips has changed from SD GlucoNavii® Mentor NFC Blood Glucose Test Strips and SD GlucoNavii® Mentor NFC Multi Blood Glucose Test Strips to SD GlucoNavii® Mentor BT Blood Glucose Test Strips and SD GlucoNavii® Mentor BT Multi Blood Glucose Test Strips.
- 5) Labeling was modified to reflect the changes to the device.

## **5. INDICATION FOR USE:**

### **SD GlucoNavii® Mentor BT Blood Glucose Monitoring System**

SD GlucoNavii®Mentor BT 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 BT 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 BT Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The SD GlucoNavii®Mentor BT 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 BT Blood Glucose Test Strips are for use with SD GlucoNavii®Mentor BT 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 BT Multi Blood Glucose Monitoring System**

SD GlucoNavii®Mentor BT 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 BT 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 BT Multi Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The SD GlucoNavii®Mentor BT 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 BT Multi Blood Glucose Test Strips are for use with SD GlucoNavii®Mentor BT 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. COMPARISON TO PREDICATE DEVICE:

The subject devices are substantially equivalent to SD GlucoNavii® Mentor NFC and Mentor NFC Multi Blood Glucose Monitoring System, cleared under K132929. Both the subject and predicate devices are the same in intended uses and basic fundamental scientific technology.

Please refer to the following similarities and difference comparison chart:

Similarities and Differences					
Item	Unmodified device (K132929)		Modified(subject) device (K153201)		Discussion of Differences
Trade Name	SD GlucoNavii® Mentor NFC Blood Glucose Monitoring System	SD GlucoNavii® Mentor NFC Multi Blood Glucose Monitoring System	SD GlucoNavii® Mentor BT Blood Glucose Monitoring System	SD GlucoNavii® Mentor BT Multi Blood Glucose Monitoring System	<i>different</i>
Manufacturer	SD Biosensor, Inc.		SD Biosensor Inc.		<i>identical</i>
Product Code	CGA, NBW		CGA, NBW		<i>identical</i>
Indications for Use	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	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	SD GlucoNavii® Mentor BT 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 BT 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 BT Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The SD	SD GlucoNavii® Mentor BT 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 BT 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 BT Multi Blood Glucose Monitoring System should not be used for the	<i>identical</i>

Similarities and Differences					
Item	Unmodified device (K132929)		Modified(subject) device (K153201)		Discussion of Differences
	<p>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.</p> <p>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.</p>	<p>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.</p> <p>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.</p>	<p>GlucoNavii®Mentor BT 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).</p> <p>SD GlucoNavii® Mentor BT Blood Glucose Test Strips are for use with SD GlucoNavii® Mentor BT Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, or palm.</p>	<p>diagnosis of or screening for diabetes. The SD GlucoNavii® Mentor BT 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).</p> <p>SD GlucoNavii® Mentor BT Multi Blood Glucose Test Strips are for use with SD GlucoNavii® Mentor BT Multi Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, or palm.</p>	
Test Time	5 seconds				identical
Measuring Range	20-600 mg/dL				identical
Operating Temperature	10-45°C (50-113°F) for blood sample / 18-30°C (64-86°F) for control solution				identical
Operating Humidity	15-95% RH				identical
Operating Altitude	up to 11,351ft.				identical
Hematocrit	20-60%				identical
Memory Capacity	300 test results		100 test results		different
Coding	N/A				identical
Meter Dimensions	50mm x 93mm x 18mm				identical
Meter Weight	50g with battery				identical

<b>Similarities and Differences</b>			
<b>Item</b>	<b>Unmodified device (K132929)</b>	<b>Modified(subject) device (K153201)</b>	<b>Discussion of Differences</b>
Unit of measure	<i>mg/dL</i>		<i>identical</i>
Sample type	<i>Fresh capillary whole blood</i>		<i>identical</i>
Sample sites	<i>Fingertip, palm, forearm or upper arm</i>		<i>identical</i>
Sample volume	<i>0.3 µL</i>		<i>identical</i>
Monitor	<i>LCD display</i>		<i>identical</i>
Backlight	<i>No</i>		<i>identical</i>
Power Supply	<i>3V CR2032 Battery x1(Replaceable)</i>		<i>identical</i>
Power Saving	<i>Automatic shut off after 1 minute of inactivity WITHOUT inserting test strip / after 3 minutes of inactivity WITH test strip inserted</i>		<i>identical</i>
Battery Life	<i>Approximately 1,000 Tests</i>		<i>identical</i>
Test Strip Technology	<i>Glucose Oxidase (GOD)</i>		<i>identical</i>
Test Principle	<i>Electrochemical biosensor</i>		<i>identical</i>
Sample Application	<i>Test strip capillary draw</i>		<i>identical</i>
Calibration	<i>Plasma-calibrated</i>		<i>identical</i>
Test Strip Storage Temperature	<i>2-32°C(36-90°F)</i>		<i>identical</i>
Test Strip Storage Humidity	<i>10-95%RH</i>		<i>identical</i>
PC link Feature	Yes, USB Cable or NFC	Yes, NFC, or Bluetooth	<i>different</i>
Smart device link Feature	Yes, NFC	Yes, NFC or Bluetooth	<i>different</i>

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

There are a number of differences between the unmodified devices and the modified devices as presented in the table above in section 6, however, the differences were evaluated through design control, risk analysis and verification & validation activities, and test results demonstrated that the differences do not raise a question of safety and effectiveness. Based on the information provided in this submission, we conclude that the modified device is substantially equivalent to the predicate device.

**8. DISCUSSION OF CLINICAL TESTS PERFORMED:**

Clinical sensitivity and clinical specificity testing are not applicable.

**9. CONCLUSION:**

Based on documentation supplied with this submission, conclusions drawn from design control, risk analysis and verification & validation activities demonstrate that the subject devices are substantially equivalent to the predicate devices.