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

October 17, 2017

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

Re: K160282
Trade/Device Name: SD LipidoCare Home System
SD LipidoCare Professional System
SD LipidoCare BT Home System
SD LipidoCare BT Professional System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CHH, JGY, LBR
Dated: October 9, 2017
Received: October 12, 2017

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,

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K160282

Device Name
SD LipidoCare BT Home System

Indications for Use *(Describe)*
SD LipidoCare BT Home 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 to measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood from the fingertip. SD LipidoCare BT Home 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).

The glucose testing system is for use by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. Glucose testing with the SD LipidoCare BT Home System should not be used for the diagnosis of or screening for diabetes and is not for use in neonates. For glucose testing, alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephoris, liver obstruction, other diseased involving lipid metabolism, or various endocrine disorders. Use the lipid profile test system at the frequency your doctor recommends testing for total cholesterol, HDL cholesterol, and triglycerides.

SD LipidoCare BT Home Blood Glucose Test Strips are for use with SD LipidoCare BT Home Analyzer to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, or upper arm by a single person and should not be shared. SD LipidoCare BT Home Lipid Profile Test Strips are intended for use with the SD LipidoCare BT Home Analyzer to quantitatively measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood 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.**

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
*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."*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K160282

Device Name
SD LipidoCare BT Professional System

Indications for Use *(Describe)*
SD LipidoCare BT Professional 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 to measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood from the fingertip. SD LipidoCare BT Professional System is intended to be used by lay-users and medical professionals. It is intended to be used by a single person and should not be shared. It is intended for testing outside the body (in vitro diagnostic use).

The glucose testing system is for people with diabetes as an aid to monitor the effectiveness of diabetes control. Glucose testing with the SD LipidoCare BT Professional System should not be used for the diagnosis of or screening for diabetes and is not for use in neonates. For glucose testing, alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephoris, liver obstruction, other diseased involving lipid metabolism, or various endocrine disorders. Use the lipid profile test system at the frequency your doctor recommends testing for total cholesterol, HDL cholesterol, and triglycerides.

SD LipidoCare BT Professional Blood Glucose Test Strips are for use with SD LipidoCare BT Professional Analyzer to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, or upper arm by lay users and medical professionals. SD LipidoCare BT Professional Lipid Profile Test Strips are intended for use with the SD LipidoCare BT Professional Analyzer to be used to quantitatively measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood by lay users and medical professionals.

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
*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."*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K160282

Device Name
SD LipidoCare Home System

Indications for Use *(Describe)*
SD LipidoCare Home 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 to measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood from the fingertip. SD LipidoCare Home 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).

The glucose testing system is for use by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. Glucose testing with the SD LipidoCare Home System should not be used for the diagnosis of or screening for diabetes and is not for use in neonates. For glucose testing, alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephoris, liver obstruction, other diseased involving lipid metabolism, or various endocrine disorders. Use the lipid profile test system at the frequency your doctor recommends testing for total cholesterol, HDL cholesterol, and triglycerides.

SD LipidoCare Home Blood Glucose Test Strips are for use with SD LipidoCare Home Analyzer to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, or upper arm by a single person and should not be shared. SD LipidoCare Home Lipid Profile Test Strips are intended for use with the SD LipidoCare Home Analyzer to quantitatively measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood 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.**

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
*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."*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K160282

Device Name
SD LipidoCare Professional System

Indications for Use *(Describe)*
SD LipidoCare Professional 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 to measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood from the fingertip. SD LipidoCare Professional System is intended to be used by lay-users and medical professionals. It is intended to be used by a single person and should not be shared. It is intended for testing outside the body (in vitro diagnostic use).

The glucose testing system is for people with diabetes as an aid to monitor the effectiveness of diabetes control. Glucose testing with the SD LipidoCare Professional System should not be used for the diagnosis of or screening for diabetes and is not for use in neonates. For glucose testing, alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephoris, liver obstruction, other diseased involving lipid metabolism, or various endocrine disorders. Use the lipid profile test system at the frequency your doctor recommends testing for total cholesterol, HDL cholesterol, and triglycerides.

SD LipidoCare Professional Blood Glucose Test Strips are for use with SD LipidoCare Professional Analyzer to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, or upper arm by lay users and medical professionals. SD LipidoCare Professional Lipid Profile Test Strips are intended for use with the SD LipidoCare Professional Analyzer to be used to quantitatively measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood by lay users and medical professionals.

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
*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."*

SD BIOSENSOR, INC.
C-4th&5th, 16, Deogyeong-Daero, 1556beon-Gil, Yeongtong-Gu,
Suwon-si, Gyeonggi-Do, KOREA, REPUBLIC OF 443-813

# 510(k) Summary

## (K160282)

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

**Date of Summary:** October 17, 2017

## 1. SUBMITTER:

### Manufacturer

SD Biosensor, Inc.
C-4th&5th, 16, Deogyeong-daero,
1556beon-gil, Yeongtong-gu, Suwon-si,
Gyeonggi-do, REPUBLIC OF KOREA 443-813
Tel : +82-31-300-0423
Fax : +82-31-300-0497

### Contact Person

Ms. SunYoung Jeong / Regulatory
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:

| | |
|---|---|
| **Proprietary Name:** | SD LipidoCare Home System<br>SD LipidoCare Professional System<br>SD LipidoCare BT Home System<br>SD LipidoCare BT Professional System |
| **Common Name:** | Blood Glucose Monitoring System<br>Cholesterol Monitoring System |
| **Classification:** | ▪ 21 CFR 862.1345, Product Code: NBW (Class II)<br>Glucose test system<br><br>▪ 21 CFR 862.1175, Product Code: CHH (Class I, meets limitations of exemptions per 21 CFR 862.9 (c)(4).)<br>Cholesterol (total) test system<br><br>▪ 21 CFR 862.1705, Product Code: JGY (Class I, meets limitations of exemptions per 21 CFR 862.9 (c)(4).)<br>Triglyceride test system |

▪ 21 CFR 862.1475, Product Code: LBR (Class I, meets limitations of exemptions per 21 CFR 862.9 (c)(4).)
Lipoprotein test system

## 3. PREDICATE DEVICES:

PTS PANELS Lipid Panel Test Strips by POLYMER TECHNOLOGY SYSTEMS, INC. (K023558)
SmartLink™ GOLD Blood Glucose Monitoring System by SD Biosensor, Inc. (K100398)

## 4. DEVICE DESCRIPTION:

SD LipidoCare (BT) Professional/Home Analyzer can measure TC, TG, HDL, and Glucose, and it also can calculate LDL and non-HDL using the blood sample from the human with the SD LipidoCare (BT) Professional/Home Lipid Profile and SD LipidoCare (BT) Professional/Home Glucose test strips. This system is portable using batteries for power source and can store up to 500 test results in the memory. Users can search the stored results and can review the average results for 7, 15 and 30 day glucose test results. The average calculation function is for glucose test results only. This system can set the beep, date, time, unit, auto printing, simplex/duplex printing, hypo warning for glucose, alarms and Bluetooth. The analyzer offers 2 models: one with Bluetooth function for printing the test results and transferring data to a PC via Bluetooth technology and the other without it. The analyzer without the Bluetooth unit can still print the test results and transfer the data to a PC using a cable.
The system includes Lipid Profile Test Strip which is based on a reflectance photometry, and Glucose Test Strip which is based on glucose oxidase biosensor.
There are also lipid check strips and glucose check strips for users to check the internal malfunction (or problem) of the analyzer prior to testing.
The code chip is for the analyzer to read the lot-specific characteristics of the test strips currently in use.
The SD Ezi Tube+ is used to apply blood sample for lipid profile testing.

## 5. INDICATION FOR USE:

**SD LipidoCare Home System**
SD LipidoCare Home 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 to measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood from the fingertip. SD LipidoCare Home 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).

The glucose testing system is for use by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. Glucose testing with the SD LipidoCare Home System should not be used for the diagnosis of or screening for diabetes and is not for use in neonates. For glucose testing, alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephoris, liver obstruction, other diseased involving lipid metabolism, or various endocrine disorders. Use the lipid profile test system at the frequency your doctor recommends testing for total cholesterol, HDL cholesterol, and triglycerides.

SD LipidoCare Home Blood Glucose Test Strips are for use with SD LipidoCare Home Analyzer to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, or upper arm by a single person and should not be shared. SD LipidoCare Home Lipid Profile Test Strips are intended for use with the SD LipidoCare Home Analyzer to quantitatively measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood by a single person and should not be shared.
**SD LipidoCare Professional System**
SD LipidoCare Professional 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 to measure total cholesterol (TC),

triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood from the fingertip. SD LipidoCare Professional System is intended to be used by lay-users and medical professionals. It is intended to be used by a single person and should not be shared. It is intended for testing outside the body (in vitro diagnostic use).

The glucose testing system is for people with diabetes as an aid to monitor the effectiveness of diabetes control. Glucose testing with the SD LipidoCare Professional System should not be used for the diagnosis of or screening for diabetes and is not for use in neonates. For glucose testing, alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephoris, liver obstruction, other diseased involving lipid metabolism, or various endocrine disorders. Use the lipid profile test system at the frequency your doctor recommends testing for total cholesterol, HDL cholesterol, and triglycerides.

SD LipidoCare Professional Blood Glucose Test Strips are for use with SD LipidoCare Professional Analyzer to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, or upper arm by lay users and medical professionals. SD LipidoCare Professional Lipid Profile Test Strips are intended for use with the SD LipidoCare Professional Analyzer to be used to quantitatively measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood by lay users and medical professionals.

**SD LipidoCare BT Home System**

SD LipidoCare BT Home 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 to measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood from the fingertip. SD LipidoCare BT Home 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).

The glucose testing system is for use by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. Glucose testing with the SD LipidoCare BT Home System should not be used for the diagnosis of or screening for diabetes and is not for use in neonates. For glucose testing, alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephoris, liver obstruction, other diseased involving lipid metabolism, or various endocrine disorders. Use the lipid profile test system at the frequency your doctor recommends testing for total cholesterol, HDL cholesterol, and triglycerides.

SD LipidoCare BT Home Blood Glucose Test Strips are for use with SD LipidoCare BT Home Analyzer to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, or upper arm by a single person and should not be shared. SD LipidoCare BT Home Lipid Profile Test Strips are intended for use with the SD LipidoCare BT Home Analyzer to quantitatively measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood by a single person and should not be shared.

**SD LipidoCare BT Professional System**

SD LipidoCare BT Professional 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 to measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood from the fingertip. SD LipidoCare BT Professional System is intended to be used by lay-users and medical professionals. It is intended to be used by a single person and should not be shared. It is intended for testing outside the body (in vitro diagnostic use).

The glucose testing system is for people with diabetes as an aid to monitor the effectiveness of diabetes control. Glucose testing with the SD LipidoCare BT Professional System should not be used for the diagnosis of or screening for diabetes and is not for use in neonates. For glucose testing, alternative site testing should be done only during

steady-state times (when glucose is not changing rapidly). Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephoris, liver obstruction, other diseased involving lipid metabolism, or various endocrine disorders. Use the lipid profile test system at the frequency your doctor recommends testing for total cholesterol, HDL cholesterol, and triglycerides.

SD LipidoCare BT Professional Blood Glucose Test Strips are for use with SD LipidoCare BT Professional Analyzer to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, or upper arm by lay users and medical professionals. SD LipidoCare BT Professional Lipid Profile Test Strips are intended for use with the SD LipidoCare BT Professional Analyzer to be used to quantitatively measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood by lay users and medical professionals.

## 6. COMPARISION TO PREDICATE DEVICE:

The SD LipidoCare (BT) Professional System and SD LipidoCare (BT) Home System are substantially equivalent to PTS PANELS Lipid Panel Test Strips (K023558, K022401) and SmartLink™ GOLD Blood Glucose Monitoring System (K100398).
The subject and the predicate devices are similar in intended use and basic fundamental scientific technology.
Please refer to the following similarities and difference comparison chart. The table below demonstrates the overall substantial equivalence of the new SD LipidoCare (BT) Professional and Home systems with the predicate devices.

### 6.1. Lipid Measurement

| Attribute | Predicate:<br>PTS PANELS Lipid Panel Test Strips | New Devices:<br>SD LipidoCare (BT)<br>Professional/Home |
|---|---|---|
| **510(k) Number** | • K023558 | - |
| **Device Names** | PTS PANELS Lipid Panel Test Strips | • SD LipidoCare (BT) Professional and Home Analyzer<br>• SD LipidoCare (BT) Professional and Home Lipid Profile Test Strip |
| **Manufacturer** | POLYMER TECHNOLOGY SYSTEMS, INC. | SD Biosensor, Inc. |
| **Intended Use** | To measure total cholesterol, triglycerides and HDL cholesterol in capillary whole blood. | Identical |
| **Assay method** | Dry chemistry | *IDENTICAL* |
| **Test time** | 1-2 minutes | 3 minutes |
| **Sample Type** | Capillary whole blood | Capillary whole blood |
| **Sample Volume** | 35-40µL | 35µL |
| **Hematocrit Range** | • TC: 30-50%<br>• TG: 15-55%<br>• HDL: 30-45% | 30-52% |
| **Test Range** | • TC: 100-400mg/dL(2.59-10.36mmol/L)<br>• TG: 50-500mg/dL(0.57-5.65mmol/L)<br>• HDL: 15-100mg/dL(0.57-2.59mmol/L) | • TC: 100-450 mg/dL(2.59-11.6mmol/L)<br>• TG: 45-650 mg/dL(0.51-7.43 mmol/L)<br>• HDL: 25-95 mg/dL(0.65-2.46 mmol/L) |
| **Operating Temp.** | 20-27°C | 64-90°F (10-90% RH) |
| **Calibration** | MEMO Chip | *IDENTICAL* |
| **Memory** | 300 tests | 500 tests |
| **Display** | LCD displays | *IDENTICAL* |
| **Power Supply** | Two 1.5V AAA Alkaline batteries | Four 1.5V AA Alkaline batteries |
| **Size** | 13.97 × 7.62 × 2.54 (cm) | 6.72 × 13.3 × 2.85 (cm) |
| **Calibration** | MEMO Chip | *IDENTICAL* |

Substantial Equivalence Discussion

1) Similarities
   - Intended Use
   - Principle of operation
   - Test Procedures
   - Display method
   - Sample Type

   *Both the predicate and the subject device have the similar intended use, principle of operation, display method, and sample type.*

2) Differences
   - Testing range
   - Hematocrit limit range
   - Operating conditions (temperature range)
   - Testing time
   - Memory capacity

   *There are differences in testing range, hematocrit limit range, operating conditions (temperature range), testing time, and memory capacity between the two devices. We performed various clinical and bench tests and the test results supported that despite these differences the subject device is substantially equivalent to the predicate devices.*

### 6.2. Glucose Measurement

| Attribute | Predicate: SmartLink™ GOLD Blood Glucose Monitoring System | New Devices: SD LipidoCare (BT) Professional/Home |
|---|---|---|
| **510(k) Number** | K100398 | - |
| **Device Names** | SmartLink™ GOLD Blood Glucose Monitoring System | SD LipidoCare Blood Glucose Test Strip |
| **Manufacturer** | SD Biosensor, Inc. | SD Biosensor, Inc. |
| **Intended Use** | For the quantitative measurement of glucose in capillary whole blood. | Identical |
| **Assay method** | Electronic chemistry | *IDENTICAL* |
| **Test time** | 5 seconds | *IDENTICAL* |
| **Sample Type** | Capillary whole blood drawn from fingertip, palm, forearm and upper arm | *IDENTICAL* |
| **Sample Volume** | 0.9uL | *IDENTICAL* |
| **Hematocrit Range** | 20-60% | *IDENTICAL* |
| **Test Range** | 20-600mg/dL(1.2-33.3mmol/L) | *IDENTICAL* |
| **Operating Temp.** | 10-45°C (50-113°F) | 64-90°F |
| **Storage Temp.** | 35-89°F | *IDENTICAL* |
| **Memory** | 500 tests | *IDENTICAL* |
| **Display** | LCD displays | *IDENTICAL* |
| **Power Supply** | CR 2032 Type | Four 1.5V AA Alkaline batteries |
| **Size** | 4.7 × 9.5 × 1.75 (mm) | 6.72 × 13.3 × 2.85 (cm) |
| **Calibration** | No-code | *IDENTICAL* |

Substantial Equivalence Discussion

1) Similarities

- Intended Use
- Principle of operation
- Test procedures
- Sample type
- Sample volume
- Various specifications

*Both the predicate and the subject device have the similar intended use, principle of operation, sample type, sample volume and various specifications.*

2) Differences
   - Size of Meter
   - Power Source
   - Operating Temp.

*There are differences in size of meter and batter type between the two devices. We performed various clinical and bench tests and the test results supported that despite these differences the subject device is substantially equivalent to the predicate devices.*

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

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.

## 8. CONCLUSION:

Based on documentation supplied with this submission, the conclusions drawn from the non-clinical and the clinical studies demonstrate that the subject devices are substantially equivalent to the predicate devices.