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 13, 2017

ALL MEDICUS CO., LTD.
C/O PRISCILLA CHUNG
LK CONSULTING GROUP, USA, INC.
800 ROOSEVELT STE 417
IRVINE CA 92620

Re: K170241
Trade/Device Name: GlucoDr.S Blood Glucose Monitoring System,
GlucoDr.S BLE Blood Glucose Monitoring System
GlucoDr.S NFC Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW
Dated: September 12, 2017
Received: September 15, 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k170241

Device Name

GlucoDr.S Blood Glucose Monitoring System

Indications for Use *(Describe)*

GlucoDr.S Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip. GlucoDr.S 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.

GlucoDr.S Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. GlucoDr.S Blood Glucose Monitoring System is not for use in neonates.

GlucoDr.S Blood Glucose Test Strips are for use with GlucoDr.S Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k170241

Device Name

GlucoDr.S BLE Blood Glucose Monitoring System

Indications for Use *(Describe)*

GlucoDr.S BLE Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip. GlucoDr.S BLE 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.

GlucoDr.S BLE Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. GlucoDr.S BLE Blood Glucose Monitoring System is not for use in neonates.

GlucoDr.S BLE Blood Glucose Test Strips are for use with GlucoDr.S BLE Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

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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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k170241

Device Name

GlucoDr.S NFC Blood Glucose Monitoring System

Indications for Use *(Describe)*

GlucoDr.S NFC Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip. GlucoDr.S 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.

GlucoDr.S NFC Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. GlucoDr.S NFC Blood Glucose Monitoring System is not for use in neonates.

GlucoDr.S NFC Blood Glucose Test Strips are for use with GlucoDr.S NFC Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

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
(k170241)

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

Date: 10/12/2017

1. **Applicant / Submitter:**

   All Medicus Co., Ltd.
   No.7102-7107, 7402, 7403, 7406, 140, Beolmal-ro, Dongan-gu, Anyang-si,
   Gyeonggi-do, 14057, Republic of Korea
   Tel: 82-31-425-8288

2. **Submission Correspondent:**

   Priscilla Chung
   LK Consulting Group USA, Inc.
   800 Roosevelt Ste 417,
   Irvine, CA 92620
   Phone: 714-202-5789 Fax: 714-409-3357
   Email: juhee.c@lkconsultinggroup.com

3. **Device:**

   - **Trade Name:**
     GlucoDr.S™ Blood Glucose Monitoring System
     GlucoDr.S™ BLE Blood Glucose Monitoring System
     GlucoDr.S™ NFC Blood Glucose Monitoring System

   - **Classification Name:**
     Blood Glucose Test System
   - **Classification regulation:**
     21 CFR Part 862.1345
   - **Product Code:**
     NBW

4. **Predicate Device:**

   GlucoDr. auto™ (K083628) by All Medicus Co., Ltd.

5. **Description:**

   The subject systems are to measure and display glucose test results. The subject meters are portable devices using a battery with capability to store 500 test results in memory, and can search the stored test results with 7, 14, 30, 60, or 90-day average value of test results. This system provides beep, hypo/hyper warning limit, date/time setting, average period, and test reminder alarms settings.

   The three systems which are GlucoDr.S™, GlucoDr.S™ BLE, and GlucoDr.S™ NFC are exactly the same devices except the data transfer features. The GlucoDr.S™ can transfer test

results to a PC or to a smart device via a USB cable only, and the GlucoDr.S™ BLE offers Bluetooth data transfer features in addition to the USB cable port. The GlucoDr.S™ NFC offers NFC data transfer features in addition to the USB cable port.

6. Indications for use:

GlucoDr.S™ Blood Glucose Monitoring System
GlucoDr.S™ Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip. GlucoDr.S™ 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.

GlucoDr.S™ Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. GlucoDr.S™ Blood Glucose Monitoring System is not for use in neonates.

GlucoDr.S™ Blood Glucose Test Strips are for use with GlucoDr.S™ Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

GlucoDr.S™ BLE Blood Glucose Monitoring System
GlucoDr.S™ BLE Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip. GlucoDr.S™ BLE 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.

GlucoDr.S™ BLE Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. GlucoDr.S™ BLE Blood Glucose Monitoring System is not for use in neonates.

GlucoDr.S™ BLE Blood Glucose Test Strips are for use with GlucoDr.S™ BLE Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

GlucoDr.S™ NFC Blood Glucose Monitoring System
GlucoDr.S™ NFC Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip. GlucoDr.S™ 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.

GlucoDr.S™ NFC Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. GlucoDr.S™ NFC Blood Glucose Monitoring System is not for use in neonates.

GlucoDr.S™ NFC Blood Glucose Test Strips are for use with GlucoDr.S™ NFC Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

7. Comparison to the Cleared Device

GlucoDr.S™, GlucoDr.S™ BLE, and GlucoDr.S™ NFC Blood Glucose Monitoring Systems are substantially equivalent to the GlucoDr™ auto Blood Glucose Monitoring System (K083628) made by our company. The table below lists the similarities and differences between the subject devices and the predicate device.

Similarities

Item	Subject Device			Predicative Device
	GlucoDr.S™ (AGM-513S)	**GlucoDr.S™ BLE (ABM-513S)**	**GlucoDr.S™ NFC (ANM-513S)**	**GlucoDr. auto™ (AGM-4000)**
510k	k170241	k170241	k170241	K083628
Manufacturer	All Medicus	All Medicus	All Medicus	All Medicus
Intended Use	**GlucoDr.S™ Blood Glucose Monitoring System** GlucoDr.S™ Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip. GlucoDr.S™ 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. GlucoDr.S™ Blood Glucose Monitoring System should not be used for the diagnosis of or	**GlucoDr.S™ BLE Blood Glucose Monitoring System** GlucoDr.S™ BLE Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip. GlucoDr.S™ BLE 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. GlucoDr.S™ BLE Blood Glucose Monitoring System should not be used for the	**GlucoDr.S™ NFC Blood Glucose Monitoring System** GlucoDr.S™ NFC Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip. GlucoDr.S™ 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. GlucoDr.S™ NFC Blood Glucose Monitoring System should not be used for the	The GlucoDr. auto™ blood glucose monitoring system system is intended for in vitro diagnostic use (i.e., for external use only) for quantitative measurement of glucose in venous, arterial and capillary whole blood. Testing sites include traditional fingertip site along with palm, upper arm, forearm, thigh, and calf. The GlucoDr. auto™ blood glucose monitoring system may be used by healthcare professionals or for self testing by diabetic lay users in the mellitus at home as aid in monitoring the effectiveness of diabetes control program. The GlucoDr. auto™ blood

	screening for diabetes. GlucoDr.S™ Blood Glucose Monitoring System is not for use in neonates. GlucoDr.S™ Blood Glucose Test Strips are for use with GlucoDr.S™ Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.	diagnosis of or screening for diabetes. GlucoDr.S™ BLE Blood Glucose Monitoring System is not for use in neonates. GlucoDr.S™ BLE Blood Glucose Test Strips are for use with GlucoDr.S™ BLE Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.	diagnosis of or screening for diabetes. GlucoDr.S™ NFC Blood Glucose Monitoring System is not for use in neonates. GlucoDr.S™ NFC Blood Glucose Test Strips are for use with GlucoDr.S™ NFC Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.	glucose monitoring system is not intended for the diagnosis of or screening for diabetes mellitus, nor intended for use on neonates.
Detection Method	Amperometry	Amperometry	Amperometry	Amperometry
Enzyme	Glucose Dehydrogenase	Glucose Dehydrogenase	Glucose Dehydrogenase	Glucose Dehydrogenase
Test Time	5 seconds	5 seconds	5 seconds	5 seconds
Sample Volumes	0.5 μℓ	0.5 μℓ	0.5 μℓ	0.5 μℓ
Test Range	20 ~ 600 mg/dL	20 ~ 600 mg/dL	20 ~ 600 mg/dL	20 ~ 600 mg/dL
Operation temperature range	10 ~ 40℃	10 ~ 40℃	10 ~ 40℃	10 ~ 40℃
Strip Storage Condition	1 ~ 32℃ 15~85%RH	1 ~ 32℃ 15~85%RH	1 ~ 32℃ 15~85%RH	1 ~ 32℃
Battery Type	3 V Lithium Battery (CR2032)	3 V Lithium Battery (CR2032)	3 V Lithium Battery (CR2032)	3 V Lithium Battery (CR2032)
Memory Capacity	500 results with date and time	500 results with date and time	500 results with date and time	500 results with date and time

Difference

Coding of Strip	no-coding	no-coding	no-coding	Auto-coding
Specimen Type	fresh capillary whole blood	fresh capillary whole blood	fresh capillary whole blood	Capillary and Venous blood
Hematocrit range	20~65%	20~65%	20~65%	20~60%
Operating Humidity Range	15~85%	15~85%	15~85%	Below 85%

Size of Meter	87.3×50×17.5mm(LWH)	87.3×50×17.5mm(LWH)	87.3×50×17.5mm(LWH)	93.5×49×17.5mm(LWH)
Weight of Meter	47.2g(with battery)	47.2g(with battery)	47.2g(with battery)	40g(with battery)
Altitude	10,000feet	10,000feet	10,000feet	8,202feet
Data transfer	Micro USB	Micro USB BLE(Bluetooth Low Energy)	Micro USB NFC(Near Field Communication)	USB

There are a number of differences between the subject devices and the predicate device as presented in the table above such as in coding, specimen type, hematocirt range, operating condition, size/weight of meter, etc..., 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 devices are substantially equivalent to the predicate device.

8. Performance Data

Bench studies including evaluation of analytical performance as well as clinical performance studies were conducted. Software verification testing was carried out to ensure all meter functions and displayed error messages perform as intended.

a. Precision Evaluation Study

Following CLSI EP05-A2, repeatability testing was conducted using 5 venous blood samples with glucose concentrations spanning the measuring range. Each measured in 10 replicates with 3 test strips lots and 10 meters. Intermediate precision testing was conducted over 14 days using 5 glucose control solutions each measured in 10 replicates with 3 test strips lots and 10 meters. GlucoDr.S™ meter results of venous blood samples were compared to those obtained by the YSI 2300 analyzer as the reference method.

(i) Repeatability evaluation

Samples	Acceptance Criteria	Pooled STD (mg/dL)	Pooled CV (%)
Level 1 (39.1 mg/dL)	STD < 4 mg/dL	2.7	6.3
Level 2 (85.5 mg/dL)	STD < 4 mg/dL	3.2	3.9
Level 3 (121 mg/dL)	CV < 4%	4.2	3.7
Level 4 (205 mg/dL)	CV < 4%	6.3	3.4
Level 5 (352 mg/dL)	CV < 4%	11.7	3.7

(ii) Intermediate Precision evaluation

Samples	Acceptance Criteria	Pooled STD (mg/dL)	Pooled CV (%)
Level 1 (37.2 mg/dL)	STD < 4 mg/dL	1.4	3.7
Level 2 (80.4 mg/dL)	STD < 4 mg/dL	1.8	2.2
Level 3 (118 mg/dL)	CV < 4%	2.6	2.2
Level 4 (200 mg/dL)	CV < 4%	3.5	1.7
Level 5 (353 mg/dL)	CV < 4%	7.4	2.1

The results of both repeatability and intermediate precision testing demonstrate that the performance of the GlucoDr.S™ meter is substantially equivalent to the predicate devices in the market.

b. Linearity Evaluation Study

Following CLSI EP6-A, linearity testing of the measuring range was conducted using 3 lots of GlucoDr.S™ blood glucose test strips. Venous blood samples were spiked to 15 levels of glucose concentrations ranging from 16 to 646.5 mg/dL and the GlucoDr.S™ meter test results were compared to those obtained from the YSI 2300 analyzer as the reference method.
A linear regression analysis of the glucose measurements resulted in a mean slope ranging from 0.97622 to 0.99754 and an R2 value of 0.99827 to 0.99951. The results support the claim that the GlucoDr.S™ Blood Glucose Monitoring System is linear between 20 and 600 mg/dL, a claim equivalent to that made for the predicate device.

c. Interferences - Endogenous/Exogenous Substances

Interference testing followed the CLSI EP7-A2. A total of 30 potential interfering

substances were evaluated using 3 lots of test strips at 3 glucose concentrations of venous blood samples, 10 replicates each. Study results indicate that the maximum allowable limit of some interfering substances for our system is as follows: Dopamine (3 mg/dL), Gentisic acid (10 mg/dL), Maltose (5,000 mg/dL), Tolazamide (16 mg/dL), Xylose (11 mg/dL), and uric acid (8 mg/dL).

d. Interferences – Hematocrit

Hematocrit levels were evaluated using 3 lots of blood glucose test strips. Samples were prepared ranging in HCT from 20 to 65% at 6 glucose concentration levels of venous blood samples, 10 replicates each. The GlucoDr.S™ results were compared to the YSI 2300 analyzer as the reference method. Study results indicate that the measurements of the GlucoDr.S™ meter were within acceptance criteria for the entire HCT range of 20-65%.

e. Sample Volume

A study was conducted to evaluate sample volumes using 3 lots of blood glucose test strips. Venous blood samples were tested at 4 glucose concentration levels and at 3 sample volumes ranging from 0.40 to 0.50 µL. Study results demonstrated that when sample volumes were less than 0.50µL, the GlucoDr.S™ meter displayed an error message. At sample volume, 0.50µL, all GlucoDr.S™ meter test results supported a minimum sample volume of 0.50 µL for the GlucoDr.S™ meter.

f. Other Bench Performance studies

Additional bench studies were conducted including:

- **Temperature and Humidity Effects**. The operating temperature range and operating relative humidity (RH) were evaluated placing GlucoDr.S™ the meter and strips in environmental chambers varying in temperature between 10 and 40°C and between 15 and 85% RH. Testing included 3 test strip lots and 4 concentrations of blood samples, each in 10 replicates. GlucoDr.S™ measurements were compared to those obtained by the YSI 2300. Results from all testing conditions support a claim of 50-104 °F (10-40°C) for the operating temperature and 15-85% for the RH.
- **Altitude Effects.** The effect of altitudes on the performance of the GlucoDr.S™ Test strip was evaluated using 4 concentrations of venous blood samples. Testing was conducted at altitudes varying between 0 and 10,020 ft. At each altitude, GlucoDr.S™ blood test results were compared to those of the YSI 2300. The results support the claim that the GlucoDr.S™ system can be operated at altitudes up to 10,020 ft.

- **Cleaning and Disinfecting.** The effect of the CaviWipes Disinfecting Towelettes was evaluated on five GlucoDr.S™ meters following cleaning and disinfecting cycles after testing blood samples. Robustness studies were performed demonstrating that there was no change in performance or in external materials of the meter after cycles of cleaning and disinfecting with the CaviWipes Disinfecting Towelettes.

- **Virucide Efficacy.** The efficacy of the recommended disinfection against Hepatitis B virus (HBV) was evaluated on the materials of the GlucoDr.S™ meter. 2 minutes contact time of meter materials with the CaviWipe Disinfecting Towelettes produced results demonstrate effective inactivation of HBV when used to disinfect the

GlucoDr.S™ meter materials.

- **Test Strip stability.** Open vial and shelf life stability of the GlucoDr.S™ test strip are assessed using real time and accelerated studies. The test results support the claimed stability durations when stored at 4-300C and at 34°F to 90°F (1-32°C) and the relative humidity 15 to 85%.

- **Readability Assessment of labeling.** A Flesch-Kincaid reading level assessment was conducted demonstrating that the User's Manual and the Test Strip Insert were written at or below an 8th grade reading level.

g. Accuracy Studies

Lay User Study

The user performance for the GlucoDr.S™ Blood Glucose Monitoring System was evaluated by using capillary blood samples from 405 patients with those obtained using a YSI Model 2300 STAT Plus Glucose Analyzer.

User performance results for glucose concentration < 75 mg/dL_Lay users

Site	Lot	Within ± 5 mg/dL	Within ± 10 mg/dL	*Within ± 15 mg/dL*
Site1	E15D23213	0/1(0%)	1/1(100%)	1/1(100%)
Site2	E15D23213	7/7(100%)	7/7(100%)	7/7(100%)
Site3	E15D23213	5/7(71.4%)	7/7(100%)	7/7(100%)
Total	**E15D23213**	**12/15(80%)**	**15/15(100%)**	**15/15(100%)**

User performance results for glucose concentration ≥ 75 mg/dL_Lay users

	Lot	Within ± 5 %	Within ± 10 %	*Within ± 15 %*
Site1	E15D23213	103/142(72.5%)	137/142(96.5%)	142/142(100%)
Site2	E15D23213	118/161(73.3%)	156/161(96.9%)	161/161(100%)
Site3	E15D23213	71/87(81.6%)	87/87(100%)	87/87(100%)
Total	**E15D23213**	**292/390(74.9%)**	**380/390(97.4%)**	**390/390(100%)**

h. Software testing was conducted based on the level of concern that was identified using FDA's Guidance on Software validation. Analysis of the GlucoDr.S™ meter test results demonstrate that both meter functionality as well as the display of the appropriate error messages, all perform as intended.

i. Electrical Safety test and Electromagnetic Compatibility were conducted in accordance with IEC61010-1 and IEC 60601-1-2. Testing results passed acceptance criteria as prescribed by each standard.

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 are substantially equivalent to our legally marketed predicate devices.