

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY AND INSTRUMENT **COMBINATION** TEMPLATE**

**A. 510(k) Number:**

k140827

**B. Purpose for Submission:**

New device

**C. Measurand:**

Glycosylated hemoglobin (HbA1c)

**D. Type of Test:**

Quantitative, Reflectometry Immunoassay

**E. Applicant:**

SD Biosensor, Inc.

**F. Proprietary and Established Names:**

SD A1cCare System  
SD A1cCare Spoit Type Test Kit

SD HbA1c Control Set  
SD HbA1c Control Level M

**G. Regulatory Information:**

<b>Classification Name</b>	<b>Product Code</b>	<b>Device Class</b>	<b>Regulation Number</b>	<b>Panel</b>
Glycosylated hemoglobin assay	LCP	II	21 CFR 864.7470	81 Hematology
Discrete photometric chemistry analyzer for clinical use.	JJE	I	21CFR 862.2160	75 Clinical Chemistry
Quality control material (assayed and unassayed)	JJX	I	21CFR862.1660	75 Clinical Chemistry

## H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The SD A1cCare System is a reflectometry immunoassay used for the quantitative measurement of glycated hemoglobin (%HbA1c) levels in fresh fingerstick capillary blood or venous whole blood samples. This system is intended for clinical laboratory and point-of-care use to monitor long term glycemic control of persons previously diagnosed with diabetes. This test is not for screening or diagnosis of diabetes.

The SD A1cCare Spoit Type Test Kit is part of the SD A1cCare System. It includes the test panel that receives the blood sample and is used with the SD A1cCare Analyzer for the quantitative measurement of glycated hemoglobin (HbA1c) levels in fresh fingerstick capillary or venous whole blood samples. The system is intended for clinical laboratory and point-of-care use to monitor long term glycemic control in persons previously diagnosed with diabetes. This test is not for screening or diagnosis of diabetes.

The SD HbA1c Control Set (Level 1, Level 2) and SD HbA1c Control Level M are intended for use as quality control material for the SD A1cCare System.

3. Special conditions for use statement(s):

- For prescription use only
- For professional use in clinical laboratory and point-of-care settings
- This test is not for screening or diagnosis of diabetes.
- Only for in-vitro diagnostic use
- Extreme Hematocrit (below 25% or over 65%) may affect the test result.
- If the total hemoglobin result is out of the range of 7-23g/dL, the test result may be affected.
- Do not use frozen blood or artificial materials.
- This test should not be used in monitoring daily glucose control
- Should not be used to replace daily home testing of urine and blood glucose levels
- Should not be used for analyzing samples from patients with conditions causing shortened red blood cell survival, such as hemolytic diseases, pregnancy and significant acute or chronic blood loss
- Hemoglobinopathies may interfere with glycated hemoglobin analysis. The results from the SD A1cCare System show that there is no significant interference for Hemoglobin C ( $\leq 40.3\%$ ), Hemoglobin D ( $\leq 35.5\%$ ), Hemoglobin E ( $\leq 30.5\%$ ), Hemoglobin S ( $\leq 40\%$ ) and Hemoglobin F ( $\leq 20.5\%$ ).

4. Special instrument requirements:

SD A1cCare Analyzer

**I. Device Description:**

The SD A1cCare Professional System is a reflectometry immunoassay system. The SD A1cCare Analyzer comes in a separate package. The SD A1cCare Spoit Type Test Kit can be used with the analyzer to form the SD A1cCare System. The system is composed of the following elements:

SD A1cCare Analyzer Package:

- Analyzer
- Check strip (to check the normal function of the optic sensor of the analyzer)
- AC adapter
- User Guide

SD A1cCare Spoit Type Test Kit:

- 20 Test Kits. Each Test Kit contains:
  - 1 Test Panel (blood mixture is applied, reacts with internal chemistry, and is read by the optical reflectometry system of the analyzer)
  - 1 Spoit (Each spoit contains a latex tablet with blue conjugates for detection of HbA1c. The spoit is used to acquire the 5uL blood sample by capillary action and to mix blood and buffer solution together.)
  - Desiccant
- 20 Buffer tubes (contain buffer solution that lyses erythrocytes and is used to prepare the blood mixture for the immunoassay reaction)
- 1 Code chip (to calibrate the analyzer for the enclosed Test Panels)
- 1 Package insert
- Optional: SD HbA1c Control Level M (there will be two package types: one package including the Control Level M and the other without it)

The SD HbA1c Control Set (Levels 1, 2) must be purchased separately.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

A1cNow+

2. Predicate 510(k) number(s):

k090413

k110056

3. Comparison with predicate:

<b>Similarities and Differences – System</b>		
<b>Item</b>	<b>SD A1cCare System (Candidate Device)</b>	<b>A1cNow+ (Predicate Device – k090413)</b>
Intended Use	The SD A1cCare System is intended for professional use to monitor long term glycemic control in people with diabetes.	Same
Appearance System		
Appearance Test panel		
Assay method	Immunoassay	Same
Sample Type	Fingerstick capillary or venous whole blood	Same
Sample Volume	5µL	Same
Sample Preparation Tools	Spoit, Buffer Tube 	Lancet, Blood Collector, Shaker 
Test time	3 minutes	5 minutes
HbA1c Test Range	4.0-15.0%	4.0-13.0%

Hematocrit Range	25-65%	20-60%
Testing Temperature	59-104°F (15-40°C)	64-82°F (18-28°C)
Storage Temperature for Test Kit	34-86°F (1-30°C)	64-82°F (18-28°C)
Power Supply	4x 1.5V AA Alkaline batteries or AC Adapter	Built-in, non-replaceable batteries
Size	5" x 3.8" x 2"	Approx. 3" x 2" x 3/4"
Calibration	Code chip with lot-specific calibration for associated Test Kits	User must ensure that the lot number of the disposable meter and the disposable test cartridges match. There is no separate calibration device.
Analyzer Quality Control	Check strip for assessing optical functionality of analyzer	Internal quality control mechanism

<b>Similarities and Differences - Controls</b>		
Items	SD A1cCare Control Set and SD HbA1c Control Level M (Candidate Device)	Afinion HbA1c Controls (Predicate Device – k110056)
Intended Use	Intended for use as quality control materials	Same
Format (Material)	Liquid ready-to-use solutions	Liquid, ready-to-use solutions
Levels	Level 1 (low), Level 2 (high), Level M (intermediate)	Level 1, Level 2
Storage Conditions	1-30°C and 10-90% R.H.	2-8°C
Use Lifetime	Single-use	60 days after opening

**K. Standard/Guidance Document Referenced (if applicable):**

EN 13640 - Stability testing of in vitro diagnostic reagents

CLSI C44-A - Harmonization of Glycohemoglobin Measurement (in vitro diagnostic)

IEC 61326-2-6 - Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements -IVD medical Equipment

IEC 61010-1 - Safety requirements for electrical equipment for measurement, control, and

laboratory use - Part 1: General requirement

CLSI EP09-A2 - Method Comparison and Bias Estimation Using Patient Samples.

CLSI EP05-A2 - Evaluation of Precision Performance of Quantitative Measurement Methods

NCCLS EP6-A - Evaluation of Linearity of Quantitative Analytical Methods

NCCLS EP7-A - Interference Testing in Clinical Chemistry

EN 61326-1 - Electrical equipment for measurement, control and laboratory use-

EMC requirements- Part 1: General requirement

IEC 61010-2-101 - Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

CLSI EP17-A2, - Evaluation of detection capability for clinical laboratory measurement procedures; approved guideline – second edition

#### **L. Test Principle:**

The SD A1cCare System is based on immunoassay technology. Chemical and immune-reactions that occur in the test panel are measured by an optical system in the analyzer, which is a reflectometer.

A code chip provides the analyzer the lot-specific characteristics of the test panel packaged with the code chip.

A whole blood sample is collected and prepared by adding it to a buffer solution and mixing it with a latex-tablet, which contains blue microspheres conjugated with a hemoglobin-specific antibody. During this preparation process, the erythrocytes are lysed to release the glycated hemoglobin (hereafter HbA1c).

The test panel is inserted into the analyzer. Next the blood mixture is introduced into the sample port of the test panel. The blood mixture fluid migrates along the channel in the test panel. HbA1c bound to the blue conjugate in the mixture is captured at the HbA1c Assay Zone Test Line by the anti-HbA1c antibody immobilized on the membrane of the test panel. The HbA1c LED illuminates the HbA1c Assay Zone Test Line and the HbA1c Detector measures the reflected light. The amount of blue conjugates captured at the HbA1c Assay Zone Test Line reflects the amount of HbA1c in the sample.

## M. Performance Characteristics (if/when applicable):

### 1. Analytical performance:

#### a. *Precision/Reproducibility:*

Internal precision studies were performed according to CLSI EP5-A2. Within-run precision studies were performed over 1 day using 3 lots of the test kits with 10 analyzers. 10 replicates were tested per analyzer, test strip lot, and % HbA1c for a total of N=100 per test kit lot. Samples were venous whole blood collected in commercially available vacuum containers treated with K<sub>2</sub> EDTA.

Intermediate (between-day) internal precision studies were performed over 10 days using 3 lots of the test kits with 10 analyzers. 10 replicates were tested per analyzer, test strip lot, and % HbA1c for a total of N=100 per test kit lot. Samples were commercially available control solutions.

All internal precision testing was performed at HbA1c concentrations of ~ 4.3% (Level 1), ~ 6.2% (Level 2), and ~ 14.4% (Level 3). % Hb1Ac in the venous blood samples was confirmed using a reference method (Bio-Rad Variant II, k984268).

Level	N	Lot	Within-run			Between-day		
			Mean % HbA1c	SD	% CV	Mean % HbA1c	SD	% CV
1	100	1	4.75	0.1	2.08	4.32	0.11	2.44
	100	2	4.75	0.09	1.97	4.32	0.11	2.56
	100	3	4.76	0.09	1.98	4.32	0.10	2.36
2	100	1	6.32	0.1	1.58	6.33	0.15	2.29
	100	2	6.29	0.11	1.77	6.28	0.14	2.3
	100	3	6.28	0.11	1.8	6.28	0.14	2.17
3	100	1	14.18	0.17	1.19	14.25	0.23	1.59
	100	2	14.17	0.16	1.16	14.29	0.24	1.69
	100	3	14.11	0.18	1.29	14.23	0.24	1.68

#### Point-of-care precision study

Point-of-care precision studies were conducted as described above at 3 clinical sites with 3-4 intended use operators per site. For the within-run study, venous whole blood samples were collected in commercially available K<sub>2</sub> EDTA tubes. For intermediate (between-day) point-of-care precision, testing was performed using commercially available control solutions.

All point-of-care precision testing was performed at HbA1c concentrations of ~ 4.4% (Level 1), ~ 6.1% (Level 2), and ~ 14.3% (Level 3). % Hb1Ac in the venous blood samples was confirmed using a reference method (Bio-Rad Variant II, k984268).

Level	N	Site	Within-run			Between-day		
			Mean % HbA1c	SD	% CV	Mean % HbA1c	SD	% CV
1	100	1	4.34	0.12	2.66	4.32	0.11	2.51
	100	2	4.27	0.11	2.48	4.39	0.1	2.24
	100	3	4.24	0.10	2.35	4.38	0.12	2.78
2	100	1	6.13	0.11	1.83	6.12	0.15	2.44
	100	2	6.09	0.1	1.67	6.05	0.14	2.31
	100	3	6.14	0.11	1.83	6.04	0.14	2.33
3	100	1	14.11	0.25	1.77	14.33	0.24	1.65
	100	2	14.18	0.24	1.7	14.24	0.24	1.71
	100	3	14.13	0.23	1.65	14.23	0.24	1.7

b. *Linearity/assay reportable range:*

Linearity was evaluated according to CLSI EP06-A. The linearity of the SD A1cCare System was verified using 11 K<sub>2</sub> EDTA venous whole blood samples from patients with and without diabetes covering the assay range. All dilutions were analyzed once on 5 analyzers using a total of 3 test kit lots. The mean observed % HbA1c value was determined for each dilution and plotted versus the relative analyte concentration (approximately 3.8, 4.7, 6.2, 7.4, 8.5, 9.7, 10.5, 11.8, 13.1, 14.5, and 15.4 % for each test type). The linear regression is as follows:

	Slope	Y-intercept	R	R <sup>2</sup>
<b>Lot 1</b>	0.9925	0.2313	0.9977	0.9955
<b>Lot 2</b>	0.9956	0.1465	0.9972	0.9945
<b>Lot 3</b>	0.9873	0.2221	0.9970	0.9941

The study supports the sponsor's claimed linearity range of 4.0-15% HbA1c for the SD A1cCare System using the Spoit Type Test Kit.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability:

The SD A1cCare System for use with the Spoit Type Test Kit is certified with the National Glycohemoglobin Standardization Program (NGSP). The NGSP certification expires in one year. See NGSP website for current certification at <http://www.ngsp.org>.

Value Assignment:

The analytical values for each production lot of the SD HbA1c Control Set and the SD HbA1c Control Level M are confirmed by comparison to the Internal Reference

measured on the Bio-Rad Variant II (k984268) in order to maintain lot-to-lot variability within close tolerances. Expected values are as follows:

Control Level	Concentration Range
Level 1	4.3 – 6.7
Level 2	7.5 – 11.5
Level M	6.0 – 8.6

Calibration:

Calibration is obtained by using a calibration code chip. The master calibration card is traceable to International Federation of Clinical Chemistry (IFCC) reference materials. Each kit contains a calibration code chip.

Stability:

Real time stability studies for the SD A1cCare Analyzer are ongoing.

Real time stability protocols for the SD A1cCare Spoit Type Test Kit were reviewed and support a shelf life claim at 34-86°F (1-30°C) and 10-90% R.H. for 18 months.

Real time and accelerated stability protocols were reviewed and support a shelf life claim for the SD HbA1c Control Set (Level 1 and 2) and SD HbA1c Control Level M at 1-30°C and 10-90% R.H. for 18 months.

The sponsor tested sample stability for venous whole blood collected in K<sub>2</sub> EDTA, Sodium/Lithium Heparin, and Sodium Fluoride tubes as well as for capillary whole blood samples. Venous blood samples can be used for testing on the SD A1cCare System for up to 8 hours when stored at room temperature (20-25°C) or up to 3 days when stored at 1-4°C. Capillary blood samples should be used for testing within 3 minutes after collection.

*d. Detection limit:*

The claimed measuring range of 4.0-15.0% HbA1c for the SD A1cCare System is based on linearity. See section 1b above.

*e. Analytical specificity:*

An interference study was performed to assess common or known endogenous and exogenous substances that could interfere with the SD A1cCare System. The potential interferents listed below were spiked into K<sub>2</sub> EDTA venous whole blood samples with different levels of % HbA1c (5.3% and 9.1%). The % HbA1c values of the spiked samples were compared to reference samples (samples containing no interferent). Samples were tested in quadruplicate and non-significant interference

was defined as  $\leq \pm 7\%$  difference relative to the reference sample.

<b>Substance</b>	<b>Highest Concentration tested at which no interference was observed</b>
Acetylsalicylic Acid	30 mg/dL
Ascorbic acid	10 mg/dL
Acetaminophen	30 mg/dL
Bilirubin	20 mg/dL
Caffeine	30 mg/dL
Hydroxyzine dihydrochloride	30 mg/dL
Triglycerides	900 mg/dL
Glyburide	20 mg/dL
Ibuprofen	50 mg/dL
Dopamine	2 mg/dL
Rheumatoid Factor	600 IU/mL
Metformin	5.1 mg/dL
Glibenclamide	0.2 mg/dL
Labile A1c	2000 mg/dL
Acetylated hemoglobin	200 mg/dL
Carbamylated hemoglobin	20 mg/dL

Total hemoglobin:

The effect of different levels of total hemoglobin was evaluated using venous whole blood samples collected in K<sub>2</sub> EDTA tubes with total hemoglobin levels of 5.1 – 24.5g/dL (5.1, 7.0, 9.3, 13.2, 17.0, 20.4, 22.2, and 24.5g/dL) spiked with HbA1c to achieve concentrations to cover the ranges of 4-5.5%, 5.5- 8.5%, and 8.5-15.0% HbA1c. Results of samples at each level of total hemoglobin were compared to results from samples with the same % HbA1c concentration tested on the Bio-Rad Variant II (k984268). The data supports the claimed hematocrit range of 7.0 – 23.0g/dL.

Hemoglobin variants:

A hemoglobin variant study was performed using venous whole blood samples collected in K<sub>2</sub> EDTA tubes (4-6%, 6-8%, and 8.1-15% HbA1c) containing known levels of hemoglobin variants C, D, E, S, and F. The samples were tested for % HbA1c in duplicate using the SDA1cCare System and results were reported as % difference compared to results obtained on the reference method (Bio-Rad Variant II Turbo HbA1c Kit 2.0, k142448). Non-significant interference was defined as  $\leq \pm 6\%$  difference between the candidate and reference method.

The testing results indicate that there is no significant interference for Hemoglobin C ( $\leq 42.10\%$ ), Hemoglobin D ( $\leq 41.10\%$ ), Hemoglobin E ( $\leq 31.25\%$ ), Hemoglobin S ( $\leq 41.30\%$ ), and Hemoglobin F ( $\leq 23.05\%$ ).

The labeling contains the following statement: “The results from the SD A1cCare System show that there is no significant interference for Hemoglobin C ( $\leq 40.3\%$ ), Hemoglobin D ( $\leq 35.5\%$ ), Hemoglobin E ( $\leq 30.5\%$ ), Hemoglobin S ( $\leq 40\%$ ) and Hemoglobin F ( $\leq 20.5\%$ ).”

Hematocrit:

The effect of different hematocrit levels was evaluated using venous whole blood samples collected in K<sub>2</sub> EDTA tubes with hematocrit levels of 20-70% (20, 25, 30, 40, 50, 60, 65, and 70%). The samples were spiked with HbA1c to achieve concentrations to cover the ranges of 4-5.5%, 5.5-8.5%, and 8.5-15.0%. Results of samples at each hematocrit level were compared to results from samples with the same % HbA1c concentration tested on the Bio-Rad Variant II (k984268). The data supports the claimed hematocrit range of 25 – 65%.

*f. Assay cut-off:*

Not Applicable

2. Comparison studies:

*a. Method comparison with predicate device:*

A point-of-care method comparison study was conducted at 3 clinical sites by 3-4 intended use operators per site using a total of 10 analyzers and 1 test kit lot per site. Operators were provided with the user’s manual for instruction prior to performing the study. 210 capillary (fingerstick) and venous (K<sub>2</sub> EDTA) whole blood samples were collected from patients with or without diabetes to achieve the following distribution of % Hb1Ac levels:

Level	Number of samples per site	% HbA1c
1	20% (14/70)	4.0 - 5.5%
2	30% (21/70)	5.5 - 7.0%
3	30% (21/70)	7.0 - 8.5%
4	20% (14/70)	8.5 - 15.0%

Samples were measured in singlicate and results were calculated as % difference compared to the reference method (Bio-Rad Variant II, k984268). Linear regression analysis was performed according to CLSI EP09-A2.

Capillary blood:

	<b>N</b>	<b>Slope</b>	<b>Intercept</b>	<b>R<sup>2</sup></b>
<b>Site 1</b>	70	1.0338	-0.1731	0.9949
<b>Site 2</b>	70	0.9938	0.1191	0.9837
<b>Site 3</b>	70	1.0187	-0.0266	0.9868
<b>Combined</b>	210	1.0159	-0.0303	0.9880

Venous whole blood:

	<b>N</b>	<b>Slope</b>	<b>Intercept</b>	<b>R<sup>2</sup></b>
<b>Site 1</b>	70	0.9925	0.0712	0.9895
<b>Site 2</b>	70	0.9875	0.0892	0.9917
<b>Site 3</b>	70	1.0218	-0.1271	0.9895
<b>Combined</b>	210	1.0017	0.0042	0.9899

*b. Matrix comparison:*

50 capillary fingerstick samples as well as matched K<sub>2</sub> EDTA, sodium/lithium heparin, and sodium fluoride venous whole blood samples at % HbA1c concentrations of 4-5.5% (10 samples), 5.6-7.0% (15 samples), 7.1-8.5% (15 samples), and 8.6-15.0% (10 samples) were tested on the SD A1cCare System. K<sub>2</sub> EDTA was used as the reference anticoagulant. Results from the linear regression analysis are as follows:

	<b>Capillary</b>	<b>Sodium Heparin</b>	<b>Lithium Heparin</b>	<b>Sodium Fluoride</b>
<b>Slope</b>	0.9788	0.9800	0.9771	0.9870
<b>Intercept</b>	-0.0233	0.0175	0.0571	-0.0190
<b>R<sup>2</sup></b>	0.9789	0.9792	0.9754	0.9764

The sponsor concluded that capillary blood as well as venous whole blood collected in sodium/lithium heparin, and sodium fluoride tubes are acceptable for use with the SD A1cCare System.

3. Clinical studies:

*a. Clinical Sensitivity:*

Not Applicable

*b. Clinical specificity:*

Not Applicable

c. *Other clinical supportive data (when a. and b. are not applicable):*

Not Applicable

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:

The sponsor states the following in the Spoit Type Test Kit package insert:

The American Diabetes Association (ADA) recommendations are summarized in the following table:

<b>% HbA1c</b>	<b>Glycemic Goal</b>
< 8% (64mmol/mol)	Less stringent
< 7% (53mmol/mol)	General (Non-pregnant Adults)
< 6% (48mmol/mol)	More stringent

HbA1c values above 6.5% HbA1c (48mmol/mol) are an indication of hyperglycemia during the preceding 2 to 3 months or longer. According to the recommendations of the ADA, AbA1c values above 6.5% HbA1c (48 mmol/mol) are suitable for the diagnosis of diabetes mellitus. Patients with HbA1c values in the range of 5.7-6.4% HbA1c (39-46mmol/mol) may be at risk of developing diabetes.

American Diabetes Association. Position Statement: Standards of medical care in diabetes - 2012. Diabetes Care 2012;35 (Suppl 1):S11–S63.

American Diabetes Association Workgroup Report: International Expert Committee report on the role of the A1C assay in the diagnosis of diabetes. Diabetes Care 2009;32(7):1327–1334.

American Diabetes Association. Position Statement: Diagnosis and classification of diabetes mellitus. Diabetes Care 2010;33 (Suppl 1):S62–S69.

**N. Instrument Name:**

SD A1cCare Analyzer

**O. System Descriptions:**

1. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes \_\_\_\_\_ or No  \_\_\_\_\_

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes \_\_\_\_\_ or No  \_\_\_\_\_

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes  \_\_\_\_\_ or No \_\_\_\_\_

3. Specimen Identification:

The user can input the barcode number for the blood sample into the analyzer using an external barcode scanner which is connected to the analyzer's barcode port after the user inserts the test panel into the analyzer, and while the analyzer is waiting for blood to be applied.

4. Specimen Sampling and Handling:

The SD HbA1c System is intended to be used with venous whole blood and capillary whole blood. The whole blood sample is mixed with the provided buffer and latex tablet and then applied to the SD A1cCare Test Panel.

5. Calibration:

Calibration is obtained by using a calibration code chip. The master calibration card is traceable to International Federation of Clinical Chemistry (IFCC) reference materials. Each kit contains a calibration code chip.

6. Quality Control:

The SD HbA1c Control Set (Level 1, Level 2) and the SD HbA1c Control Level M are intended for use as quality control materials for the SD A1cCare System.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:**

Infection Control Studies:

The device is intended for professional use in clinical laboratory and point-of-care settings. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B

virus (HBV) with the chosen disinfectant, Discide Ultra Disinfecting Towelettes (EPA Registration # 10492-4). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 10,950 cleaning and 10,950 disinfection steps with the Discide Ultra Disinfecting Towelettes. The robustness studies were designed to simulate 10 cleaning and disinfection cycles per day for 3 years. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

**Q. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**R. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.