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

A. 510(k) Number:

k130094

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood, arterial, venous and neonatal blood glucose and β-ketone

D. Type of Test:

Quantitative, Amperometric method, Glucose Dehydrogenase (NAD) and β-hydroxybutyrate

E. Applicant:

Abbott Diabetes Care Inc.

F. Proprietary and Established Names:

Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System

G. Regulatory Information:

Device	Product Code	Classification	Regulation Section
Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System	NBW LFR	Class II	i) Glucose Test System (21 CFR862.1345)
	JQP	Class I, meets limitations of exemptions 862.9 (c)(5)	ii) Calculator/Data Processing Module for Clinical Use (21 CFR862.2100)
	JIN	Class I, meets limitations of exemptions 862.9(c)(5)	iii) Ketones (Nonquantitative) Test System (21 CFR 862.1435)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System

   The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger, and from venous, arterial and neonatal whole blood, and for the quantitative measurement of β-ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the finger, and from venous, arterial, and neonatal whole blood when used within 30 minutes after collection. The Freestyle Precision Pro Blood Glucose and β-Ketone 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 a diabetes control program. This system should only be used with single-use, auto-disabling lancing devices.

   The system should not be used for the diagnosis of or screening for diabetes.

   The Freestyle Precision Pro Blood Glucose Test Strips are for use with the Freestyle Precision Pro Blood Glucose and β-Ketone Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, and from venous, arterial, and neonatal whole blood. The Freestyle Precision Pro Blood β-Ketone Test Strips are for use with the Freestyle Precision Pro Blood Glucose and β-Ketone Meter to quantitatively measure β-ketone in fresh capillary whole blood samples drawn from the fingertips and from venous, arterial, and neonatal whole blood.

   Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System enables automatic transmission of stored data to a data management system using the docking station (optional), a data upload cable (optional), or wirelessly (optional) in a WiFi enabled facility when the meter and data management systems are properly configured.

3. Special conditions for use statement(s):
   - Not for screening or diagnosis of diabetes mellitus
   - Not for patients who are dehydrated, in shock or in a hyperosmolar state
   - This system has not been evaluated in the critically ill

4. Special instrument requirements:

   Freestyle Precision Pro Blood Glucose and β-Ketone Meter

I. Device Description:

The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System is a microprocessor-controlled device that algorithmically processes electrical current from a (biosensor) test strip to compute a diabetic patient's blood glucose reading.
The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System should be used with the corresponding blood Glucose and β-ketone test strips respectively. The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System consists of the following components:

- Freestyle Precision Pro Blood Glucose and β-Ketone Meter
- Freestyle Precision Pro Blood Glucose Test Strips and β-Ketone Test Strips
- Medisense Glucose and Ketone Control Solutions (previously cleared in k983504) are aqueous materials that are available separately at three levels: low, mid, and high.
- The meter automatically uploads to the data management system using the docking station, a data upload cable, or wirelessly.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Precision Xceed Pro Blood Glucose and β-Ketone Monitoring System (Abbott Diabetes Care, Inc)

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

   k080960

3. Comparison with predicate:

Similarities and Differences		
	Candidate Device	**Predicate Device**
Characteristic	**Freestyle Precision ProBlood Glucose and β-KetoneMonitoring System**	**Precision Xceed Pro BloodGlucose and β-KetoneMonitoring System (k080960)**
Indications for Use	The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger, and from venous, arterial and neonatal whole blood, and for the quantitative measurement of B- ketone (beta-hydroxybutyrate) in fresh capillary whole blood from the finger and venous, arterial, and neonatal whole blood when used within 30 minutes after collection.	Same

Test Strip Enzymes	Glucose Dehydrogenase (NAD dependent) and hydroxybutyrate	Same
Glucose Measuring Range	20-500 mg/dL	Same
Ketone Measuring Range	0.01 – 8.0 mmol/L	Same
Operating Temperature	59°-104 °F	Same
Operating Humidity	10-90%	Same
Hematocrit	30-60%	Same
Sample volume	0.6 µl	Same
Data storage	2,500 patient results 1,000 control test results	Same
Data upload	Via data cable, docking station, and wirelessly	Via data cable
Barcode scanner	1D/2D camera	Laser
Blood Glucose and Ketone assay time	5 sec – glucose 10 sec – ß-ketone	20 sec – glucose 10 sec – ß-ketone

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

CLSI EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition.

ISO 14971:2000, Medical Devices-Application of risk management to medical devices

ISO 15197, In Vitro diagnostic test systems -Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

L. Test Principle:

The Precision Xceed Pro Blood Glucose and β-Ketone Monitoring System measures glucose electrochemically. The glucose biosensor is capable of determining glucose oxidized by the enzyme (Glucose dehydrogenase, GDH-NAD) catalyzed reaction with Nicotinamide adenine dinucleotide (NAD+) cofactor. The reduced form of NAD + (NADH) is re-oxidized by reaction with the electrochemical mediator, 1,10-phenanthroline quinone (1,10-PQ). The reduced mediator is re-oxidized via electron transfer at the electrode surface. This current is translated into a number by the monitor, after applying lot specific calibration information and after a 5 second countdown, a concentration value is presented to the user. In this same manner, the biosensor electrode utilizes the enzyme hydroxybutyrate dehydrogenase (HBDH), which reacts with the beta-hydroxybutyrate (beta-ketone) concentration in the sample. This reaction is transferred to the monitor through an electrical current generated proportional to the level of beta-ketone in the sample. This current is translated into a number by the monitor, after applying lot specific calibration information and after a 10 second countdown, a concentration value is presented to the user.

M. Performance Characteristics (if/when applicable):

The meter and strips of the β-ketone assay are identical to the predicate device. While the β -ketone test strip has been previously cleared on the candidate meter, the glucose test strip has not. For this reason, performance characteristics for the only glucose assay in the candidate device are described below. Performance characteristics for the β-ketone assay of this device are described in the predicate device submission (k080960).

1. Analytical performance:

   a. Precision/Reproducibility:

   Ketone precision:
   β-ketone precision was established in its predicate k080960.

   Glucose precision:
   The repeatability study was performed using heparinized anti-coagulated venous whole blood spiked to five different glucose concentrations, 30-50, 51-110, 111-150, 151-250, and 251-400 mg/dL. Each sample was tested on ten meters using three lots of test strips. At each concentration, ten measurements were obtained per meter and test strip lot. The results are summarized below:

Glucose Level, mg/dL	Lot	N	Meter Reading	SD, mg/dL	CV, %
30-50	1	100	46	2.0	4.5
	2	100	46	2.0	4.4
	3	100	45	2.4	5.4
	Combined			2.2	4.8
	1	100	89	3.4	3.9

51-110	2	100	93	3.0	3.2
	3	100	91	3.4	3.8
	Combined			3.3	3.6
111-150	1	100	137	4.6	3.4
	2	100	140	4.0	2.9
	3	100	140	4.6	3.3
	Combined			4.4	3.2
151-250	1	100	216	6.3	2.9
	2	100	223	6.2	2.8
	3	100	223	7.1	3.2
	Combined			6.5	2.9
251-400	1	100	356	10.8	3.0
	2	100	361	8.5	2.4
	3	100	375	12.0	3.2
	Combined			10.5	2.9

Intermediate precision studies were performed using three levels of control solutions. Each sample was tested on ten meters with three different glucose control levels, low, mid, and high. Each sample was tested on ten meters using three lots of test strips. In each concentration, four measurements were obtained per meter and test strip lot. The results are summarized below:

Glucose Level	Lot	n	Meter Reading	SD, mg/dL	CV, %
1	1	40	46	2.7	5.9
	2	40	45	2.9	6.5
	3	40	43	2.9	6.6
	Combined			2.8	6.4
2	1	40	97	4.4	4.5
	2	40	98	5.2	5.3
	3	40	95	5.0	5.3
	Combined			4.9	5.0
3	1	40	305	12.8	4.2
	2	40	315	11.2	3.6
	3	40	311	11.3	3.6
	Combined			11.8	3.8

b. Linearity:

β-ketone linearity was established in its predicate k080960. The measuring range for β-ketone is 0.01-8.0 mmol/L.

Glucose linearity: In the linearity study, three blood donor samples were spiked with dextrose to include glucose concentrations of 23, 47, 78, 130, 197, 262, 336, 406, 482 mg/dL as measured by the YSI-2300. At each glucose level, 9 meters, and 10 replicates of each of 3 strip lots were tested. Values from the 9 meters were compared with those obtained from YSI. The results from regression analysis are summarized

below:

Strip Lot 1: Y = 0.96x + 1.544, R^2=0.995
Strip Lot 2: Y = 0.97x - 4.508, R^2=0.996
Strip Lot 3: Y = 0.97x - 0.591, R^2=0.997

The results of the linearity study support the claimed measuring range of 20-500 mg/dL for glucose.

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

Traceability, stability and value assignment –

Test strips:

β-Ketone test strip:
The β-ketone test strips were cleared under k080960 under the name Precision Xtra Blood β-Ketone Test Strips. The ketone test strip remains unchanged, however the brand name of the ketone strip has been updated to Freestyle Precision Pro β-Ketone Test Strip. The stability of the test strips has been established under k080960.

Glucose test strip:
The Freestyle Precision Pro Glucose Test Strips are sealed in individual foil packets. Stability information was presented for the Freestyle Precision Pro Glucose Test Strip to support an 18 month shelf life when stored at 4-30°C.

Control Solutions:

The control solutions were previously cleared and stability and value assignment was previously established in k983504.

d. Detection limit:

See the linearity study in section M. 1. b. above.

e. Analytical specificity:
The analytical specificity for β-ketone measurement was established in k080960. Interference studies were performed for the glucose measurement function by evaluating 25 potential interfering substances spiked into venous blood at two different glucose levels, 50-100 mg/dL and 250-350 mg/dL. Substances were spiked into blood samples at a normal/therapeutic and a high concentration. The control samples were not spiked with the substances. Bias from YSI was compared between the samples with and without spiked substances to determine whether a particular substance interferes with glucose measurement. The following table lists the concentrations of each substance at which no significant interference was detected:

Substances Glucose 50 – 100 mg/dL	Non-Interfering Concentration, mg/dL	Substances Glucose 250 – 350 mg/dL	Non-Interfering Concentration, mg/dL
Acetaminophen	20	Acetaminophen	20
Ascorbate	2.5	Ascorbate	5
Amoxicillin	7.5	Amoxicillin	7.5
Beta-Hydroxybutyrate	100	Beta-Hydroxybutyrate	100
Bilirubin (unconjugated)	20	Bilirubin (unconjugated)	20
Captopril	0.5	Captopril	0.5
Cholesterol	500	Cholesterol	500
Creatinine	30	Creatinine	30
Dopamine	13	Dopamine	13
EDTA	720	EDTA	720
Ephedrine	10	Ephedrine	10
Galactose	100	Galactose	100
Gentisic Acid	3.6	Gentisic Acid	3.6
Ibuprofen	50	Ibuprofen	50
L-Dopa	5	L-Dopa	5
Lactate	100	Lactate	100
Lactose	100	Lactose	100
Maltose	200	Maltose	200
Methyl-Dopa	2.5	Methyl-Dopa	2.5
Na^+	500	Na^+	500
Pyruvate	10	Pyruvate	10
Salicylic Acid	50	Salicylic Acid	50
Tetracycline	4	Tetracycline	4
Tolazamide	100	Tolazamide	100
Tolbutamide	100	Tolbutamide	100
Triglycerides	3000	Triglycerides	3000
Uric Acid	40	Uric Acid	40
Xylose	50	Xylose	100

The sponsor has the following limitations in their labeling: Ascorbate concentrations greater than or equal to 2.5 mg/dL and xylose concentrations greater than or equal to 50 mg/dL may interfere with the accuracy of the test results.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

β-ketone accuracy was established in k080960.

Glucose accuracy:
To assess system accuracy, a total of 150 capillary blood samples with glucose values ranging from 32.5 to 494 mg/dL were evaluated on each of 3 strip lots run with the FreeStyle Precision Pro Blood Glucose Test Strips and were verified using YSI reference results. To obtain low or high end glucose values, capillary blood samples were glycolyzed or spiked. Although 150 subjects were recruited for the study, 7 were excluded for protocol deviations due to early withdrawal or incomplete sampling. Therefore, only 143 samples were available for analysis for the lay user test. An additional 20 samples were manipulated samples to meet the glucose distribution across the range. Therefore, 163 samples were available for the test. The meter results relative to YSI are as follows:

Glucose results < 75mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within± 15 mg/dL
13 / 18 (72.2 %)	18 / 18 (100.0 %)	18 / 18 (100.0 %)

Glucose results ≥75 mg/dL

Within ± 5%	Within ± 10%	Within± 15%	Within ± 20%
104 / 145 (71.7 %)	137 / 145 (94.5 %)	145 / 145 (100.0 %)	145 / 145 (100.0 %)

Linear Regression Statistics (Meter Results vs. YSI Reference)

Comparison	N	Slope	Intercept (mg/dL)	R^2
vs. YSI	163	1.01	-1.3	0.994

b. Matrix comparison:

Arterial blood:

A total of 120 arterial whole blood samples with glucose values ranging from 66 to 236 mg/dL (YSI reference results) were evaluated on each of 3 strip lots run with the FreeStyle Precision Pro Blood Glucose Test Strips. The meter results relative to YSI are summarized in the tables below:

Glucose results < 75mg/dL

Within ± 5mg/dL	Within ±10mg/dL	Within ± 15 mg/dL
2 *I* 2 (100.0%)	2 *I* 2 (100.0%)	2 *I* 2 (100.0%)

Glucose results ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ± 15%	Within ± 20%
88 /118 (74.6%)	116 /118 (98.3%)	118 /118 (100.0%)	118/118 (100.0%)

Linear Regression Statistics (Meter Results vs. YSI Reference)

Comparison	N	Slope	Intercept (mg/dL)	R^2
vs. YSI	120	1.07	-9.7	0.986

Neonatal blood accuracy was as follows:

A total of 127 neonatal whole blood samples with glucose values ranging from 31 to 142 mg/dL (YSI reference results) were collected for evaluation on each of 2 strip lots run with the FreeStyle Precision Pro Blood Glucose Test Strips. Nine of the collected samples were excluded from the study for protocol deviation and therefore only 118 samples were available for the analysis. The range of hematocrit values obtained ranged from 22% to 61%. The meter results relative to YSI are summarized in the tables below:

Glucose results < 75mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
47/59 (79.7%)	59/59 (100.0%)	59/59 (100.0%)

Glucose results ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within± 15%	Within ± 20%
46 / 59 (78.0%)	54 / 59 (91.5%)	59 / 59 (100.0%)	59 / 59 (100.0%)

Linear Regression Statistics (Meter Results vs. YSI Reference)

Comparison	N	Slope	Intercept (mg/dL)	R^2
vs. YSI	118	1.04	-5.0	0.981

Venous blood accuracy was as follows:

A total of 110 EDTA and Lithium Heparin venous blood samples with glucose values ranging from 58 to 372 mg/dL (YSI reference results) were evaluated on each of 3 strip lots run with the FreeStyle Precision Pro Blood Glucose Test Strips. No manipulation was employed in this study. The meter results relative to YSI are summarized in the tables below:

Glucose results < 75mg/dL

Tube	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
EDTA	2 / 3 (66.7%)	3 / 3 (100.0%)	3 / 3 (100.0%)
Heparin	3 / 3 (100.0%)	3 / 3 (100.0%)	3 / 3 (100.0%)

Glucose results ≥ 75 mg/dL

Tube	Within ± 5%	Within ± 10%	Within± 15%	Within ± 20%
EDTA	75 / 107 (70.1%)	99 / 107 (92.5%)	106 / 107 (99.1%)	107 / 107 (100.0%)
Heparin	70 / 107 (65.4%)	100 / 107 (93.5%)	107 / 107 (100.0%)	107 / 107 (100.0%)

Linear Regression Statistics (Meter Results vs. YSI Reference)

Tube	Comparison	N	Slope	Intercept (mg/dL)	R^2
EDTA	vs. YSI	110	0.98	0.27	0.991
Heparin	vs. YSI	110	0.99	0.31	0.994

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):

To assess the performance of the FreeStyle Precision Pro Blood Glucose Monitoring System in the hands of the lay users the sponsor performed a study with 150 lay user participants. Seven were excluded for protocol deviations due to early withdrawal or incomplete sampling. Results were analyzed by comparing blood glucose results from the FreeStyle Precision Pro Blood Glucose Monitoring System obtained by the lay user against the reference value (YSI). The samples ranged from 46 to 477 mg/dL as measured by the reference method. The results are summarized in the tables below:

Glucose results < 75mg/dL

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within± 15 mg/dL
Lay User	3 / 7 (42.9 %)	7 / 7 (100.0 %)	7 / 7 (100.0 %).

Glucose results ≥ 75 mg/dL

	Within ± 5%	Within ± 10%	Within± 15%	Within ± 20%
Lay User	82 / 136 (60.3%)	123 /136 (90.4%)	132/136(97.1%)	136 / 136 (100.0%)

Linear Regression Statistics (Meter Results vs. YSI Reference)

Comparison	N	Slope	Intercept (mg/dL)	R^2
vs. YSI	143	1.01	-3.2	0.992

4. Clinical cut-off**:**

Not applicable.

5. Expected values/Reference range:

In the labeling, expected blood glucose levels for people without diabetes (referenced from American Diabetes Association Standards of Care, 2013) are presented as follows:

Before eating - less than 100 mg/dL

Two hours after meals - less than 140 mg/dL

Expected levels of β-ketones for people without diabetes (referenced from Detection of Ketosis and Monitoring Of Diabetic Ketoacidosis, H. P. CHASE, Managed Care, 13 (4), 2004, Page S5-S6) are less than 0.6 mmol/L.

N. Instrument Name:

Freestyle Precision Pro Blood Glucose and β-Ketone Meter

O. System Descriptions:

1. Modes of Operation:

   Each glucose and β-ketone test strip is single use and must be replaced with a new strip for each additional reading.

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

   Yes __X__or No _____

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

   Yes __X__or No _____

2. Software:

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

   Yes ___X_ _ or No _____

3. Specimen Identification:

   A barcode scanner of Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System is used for scanning hospital patient barcodes and strip lot barcodes. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   The Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System is intended to be used with capillary whole blood from the finger, or venous, arterial or neonatal whole blood. Since the whole blood sample is applied directly to the test strip, there are no special handling or storage issues.

5. Calibration:

   Scanning the bar code label on each glucose and ketone test strip foil packet prior to use automatically calibrates the monitor and checks the expiration date.

6. Quality Control:

   Glucose and ketone control solutions at three concentrations should be tested with this device. Acceptable ranges for each control level are printed on the respective test strip vials. The user is instructed to contact the Customer Help line if control results fall outside these ranges.

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

1. Software documentation: The following documentations related to the software were reviewed and found to be acceptable. The firm provided documentation to support the device was designed, developed and is under good software lifecycle processes.

2. Data transmission: Bench testing has been performed on two meters to verify that the meters meet the requirements of transmitting full data memory and memory rollover via wireless signal and data cable. The results showed that all data was transmitted accurately at 100% with no data corruption.

3. Hematocrit Study:
   a. Ketone: Hematocrit study for the ketone strip was previously established. The sponsor's claim is that hematocrit in the range of 30-60% does not significantly interfere with ketone results.

   b. Glucose: The effect of different hematocrit levels was evaluated with three lot of test strips. Blood samples at five concentrations (40-50, 100-120, 210-230, 330-350, 400-460 mg/dL) were analyzed. The glucose samples were prepared from venous blood at seven different hematocrit levels 15, 20, 30, 43, 50, 60, and 65%. Glucose results for each concentration and hematocrit level were compared to samples tested on the YSI reference method. The data supports the sponsor's claim that hematocrit in the range of 30-60% does not significantly interfere with glucose measurements.

4. Altitude Study:
   a. Ketone: Altitude study for the ketone strip was previously established in k983850 it says altitude up to 7200 feet does not affect results.

   b. Glucose: An altitude study was conducted to evaluate the effect of altitude up to 10,152 feet on performance of the blood glucose monitoring system. Venous whole blood samples at three glucose concentrations 40, 100, 420 mg/dL were tested on one lot of test strips. Each sample was also evaluated by the YSI method. At altitudes of 10,152 feet, there was no significant effect on the tested values verified by YSI.

5. Test System operating conditions:
   a. Ketone: Test System operating condition for the ketone strip was previously established.

b. Glucose: Studies were performed using three lots of test strips, with glucose concentrations of 40-50, 90-110 and 380-420 mg/dL. Testing was performed at five combined temperature and humidity conditions (15˚C/10% RH, 15˚C/90%RH, 24˚C/50%RH, 40˚C/10%RH and 40˚C/90%RH) and results compared to the reference YSI. There were no significant differences relative to YSI in glucose concentrations across the temperature and humidity ranges tested. Results demonstrated that the test system can be used at temperatures from 59-104˚F (15-40˚C) and at a relative humidity from 10-90%.

6. User performance study:
   During the lay user study described above in Section M.3.c, the participants were asked to complete a questionnaire to evaluate the ease of use of the device and the clarity of the English language labeling. Overall the users indicated that they could successfully perform the test and that the user manual was written clearly.

7. Readability Assessment:
   The readability of the labeling (user guide and test strip insert) using a Flesch-Kincaid analysis were found to be written at the 8th grade level.

8. EMC Testing:
   The sponsor provided the appropriate documentation certifying that acceptable electromagnetic testing (EMC) had been performed.

9. Infection Control:
   Freestyle Precision Pro Blood Glucose and β-Ketone Monitoring System is intended for multiple–patient use. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing lab demonstrating complete inactivation of hepatitis B Virus (HBV) with the chosen disinfectant, Dispatch Hospital Cleaner Disinfectant Towels with Bleach (EPA Reg. No: 56392-8). 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 disinfection cycles, using Dispatch Hospital Cleaner Disinfectant Towels with Bleach, to simulate 3 years of multiple-patient use. Labeling has been reviewed for adequate instructions in 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.