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

I Background Information:

A 510(k) Number

K213061

B Applicant

OK BioTech Co., Ltd.

C Proprietary and Established Names

SuperCheck Pro Blood Glucose Monitoring System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NBW	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Glucose in capillary whole blood from finger, forearm, upper arm, calf, thigh, or palm

C Type of Test:

Quantitative amperometric measurement of glucose (GDH-FAD)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The SuperCheck Pro Blood Glucose Monitoring System is comprised of the SuperCheck Pro Blood Glucose Meter and SuperCheck Pro Blood Glucose Test Strips. The SuperCheck Pro Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger, forearm, upper arm, calf, thigh, or palm. It is intended to be used by a single person and should not be shared. The SuperCheck Pro Blood Glucose Monitoring System is for self-testing outside the body (in vitro diagnostic use) by people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. The SuperCheck Pro Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus, nor for use with neonates. Alternative site testing should be done only during steady-state conditions (when blood glucose is not changing rapidly).

C Special Conditions for Use Statement(s):

- OTC - Over The Counter
- The Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use.
- For single patient use only. Do not use on multiple patients.
- Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.
- High altitudes above 11,161 ft (3,402 meter) may affect the test results.
- Temperatures outside the range of 50°F to 104°F (10°C to 40°C), humidity range outside 10~85% R.H. may affect the test results. Do not test beyond the temperature/humidity range.
- Do not use alternative site testing when your glucose is changing rapidly.
- Do not use alternative site testing results for CGM calibration or for insulin dose calculations.
- Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients.
- Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.

D Special Instrument Requirements:

SuperCheck Pro Blood Glucose Meter

IV Device/System Characteristics:

A Device Description:

The SuperCheck Pro Blood Glucose Monitoring System consists of:

- SuperCheck Pro Blood Glucose Meter
- SuperCheck Pro Blood Glucose Test Strips
- OKmeter Control Solution (Levels I and II)

OKmeter Control Solutions and SuperCheck Pro Blood Glucose Test Strips can be purchased separately.

B Principle of Operation:

The SuperCheck Pro Blood Glucose Monitoring System (Model OK-2MJB) quantitatively measures the amount of glucose in fresh capillary whole blood from the fingertip and alternative sites including the palm, forearm, upper arm, calf, and thigh. Blood is applied to the end tip of the test strip, and is then automatically pulled into the reaction cell through capillary action. The enzyme consisting of glucose dehydrogenase with its cofactor flavin adenine dinucleotide (GDH-FAD) and mediator deposited onto the reaction area of the test strip reacts with the glucose in the blood sample to produce an electric current, which is proportional to the amount of glucose in the sample. The meter measures the strength of the current and displays the corresponding blood glucose concentration. The meter provides plasma-equivalent results.

C Instrument Description Information:

1. Instrument Name:

   SuperCheck Pro Blood Glucose Meter

2. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

3. Specimen Sampling and Handling:

   Samples are to be tested immediately upon collection.

4. Calibration:

   The meter does not require calibration or coding by the user. The meter is automatically coded.

5. Quality Control:

The sponsor manufactures 2 levels of OKmeter Control Solutions (Levels I and II). Each test strip vial is marked with a control solution range. The labeling includes instructions to use the C key when conducting control solution testing to prevent the results from being included in the blood result averages. The user is instructed in the labeling to compare the control results with the expected control ranges printed on the strip vial. Users are given instructions on when to conduct control solution testing and to call customer service if repeat testing with control material is out of range.

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

V Substantial Equivalence Information:

A Predicate Device Name(s):

WowGoHealth Blood Glucose Monitoring System

B Predicate 510(k) Number(s):

K171785

C Comparison with Predicate(s):

Device & Predicate Device(s):	K213061	K171785
Device Trade Name	SuperCheck Pro Blood Glucose Monitoring System	WowGoHealth Blood Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the quantitative measurement of glucose in capillary whole blood by people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program.	Same
Assay method	Electrochemical	Same
Detection method	Amperometry	Same
Enzyme	Flavin adenine dinucleotide-Glucose dehydrogenase	Same

	(GDH-FAD)	
Measurement range	20 to 600 mg/dL	Same
HCT Range	20 - 60%	Same
Coding	No	Same
Data transmission	Bluetooth	Same
General Device Characteristic Differences		
Alternate-Site Testing (AST)	Forearm, upper arm, calf, thigh, or palm	Forearm
Sample volume	0.5 µL	1.1 µL
Operating Conditions	50-104°F (10~40°C), 10-85% RH	50-104°F (10~40°C), 20-80% RH

VI Standards/Guidance Documents Referenced:

- Clinical and Laboratory Standards Institute (CLSI) EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition
- CLSI EP07 Interference Testing in Clinical Chemistry - Third Edition.
- ISO 14971 Third Edition Medical Devices - Application of Risk Management to Medical Devices
- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012,Cl:2009/(R)2012 and A2:2010/(R)2012- Medical electrical equipment -Part 1: General requirements for safety and essential performance

VII Performance Characteristics (if/when applicable):

A. Analytical Performance:

1. Precision/Reproducibility:

Within-run precision:

The sponsor performed a within-run precision (repeatability) study using venous whole blood samples at 5 glucose levels (30-50, 51-110, 111-150, 151-250, 251-600 mg/dL). Each sample was tested 10 times on each of 10 meters using 3 lots of test strips for a total of 300 tests per glucose concentration. Results are summarized below:

Target Glucose Ranges, mg/dL	Lot	N	Mean, mg/dL	SD, mg/dL	CV
30 to 50	1	100	39.9	1.5	3.7%
	2	100	40	1.4	3.6%
	3	100	39.9	1.4	3.5%
	Pooled	300	39.9	1.4	3.6%
51 to 110	1	100	80	2.6	3.3%
	2	100	80	2.4	3.0%
	3	100	80	2.5	3.2%

Target Glucose Ranges, mg/dL	Lot	N	Mean, mg/dL	SD, mg/dL	CV
	Pooled	300	80	2.5	3.2%
111 to 150	1	100	131.2	4.3	3.3%
	2	100	130.4	4.1	3.1%
	3	100	131.3	4.5	3.4%
	Pooled	300	130.9	4.3	3.3%
151 to 250	1	100	201.5	5.8	2.9%
	2	100	201.6	6.6	3.3%
	3	100	202.3	6.4	3.2%
	Pooled	300	201.8	6.3	3.1%
251 to 600	1	100	308.7	9.9	3.2%
	2	100	309.3	9.6	3.1%
	3	100	308.7	9.6	3.1%
	Pooled	300	308.9	9.7	3.1%

Intermediate Precision:

Intermediate precision was evaluated for 10 days using 5 levels of control solutions, 3 test strip lots, and 10 meters. Each sample level was measured once a day with each meter and each test strip lot for 10 days, for a total of 300 replicates per level. Results are summarized below:

Control Solution Level	Lot	N	Mean, mg/dL	SD, mg/dL	CV
Level 1	1	100	45.1	1.2	2.6%
	2	100	44.8	1.1	2.6%
	3	100	45.2	1.3	2.9%
	Pooled	300	45	1.2	2.7%
Level 2	1	100	80.2	2.6	3.3%
	2	100	80.5	2.4	3.0%
	3	100	80.4	2.6	3.2%
	Pooled	300	80.3	2.6	3.2%
Level 3	1	100	129.8	3.7	2.8%
	2	100	129.8	4	3.1%
	3	100	131	4	3.0%
	Pooled	300	130.2	3.9	3.0%
Level 4	1	100	201.1	5.7	2.8%
	2	100	199.6	5.5	2.8%
	3	100	198.9	5.9	3.0%
	Pooled	300	199.9	5.8	2.9%
Level 5	1	100	324.2	9.9	3.0%
	2	100	323.9	9.4	2.9%
	3	100	325.2	9	2.8%
	Pooled	300	324.4	9.4	2.9%

2. Linearity:

The claimed measuring range of the candidate device is 20-600 mg/dL. Linearity was evaluated using 3 lots of test strips, 10 meters, and 11 venous whole blood samples with the following mean glucose concentrations when measured on the YSI 2300 comparator method: 19.8, 50.2, 90.0, 121.3, 149.3, 250.3, 351.5, 450.3, 548.8, 600.3, and 701.0 mg/dL. Blood glucose concentration values obtained on the SuperCheck Pro Blood Glucose Monitoring System were compared to those obtained using the YSI 2300 comparator method. The results of linear regression analysis are summarized below:

Lot 1: $y = 1.0055x - 1.4364$; $R^2 = 0.9995$
Lot 2: $y = 0.9992x + 0.0577$; $R^2 = 0.9999$
Lot 3: $y = 0.9993x + 1.3448$; $R^2 = 0.9998$

The results of the study support the sponsor's claimed glucose measurement range of 20-600 mg/dL.

If a glucose result is less than 20 mg/dL, "LO" is displayed on the meter. If a glucose result is more than 600 mg/dL, "HI" is displayed on the meter. The "LO" and "HI" functions were validated and demonstrated to function as intended.

3. Analytical Specificity/Interference:

To assess potential interference from endogenous and exogenous substances on glucose measurements from the SuperCheck Pro Blood Glucose Monitoring System, a study was conducted using venous whole blood samples adjusted to the following glucose levels as measured by the YSI 2300 comparator method: 51-70, 111-130, and 225-270 mg/dL. Each of these samples was divided into a test pool and a control pool, with each of the potential endogenous and exogenous interfering substances added to the test pool. Four (4) levels of each of the potentially interfering substances were prepared and tested using 3 lots of test strips and 10 meters, for a total of 30 replicates per test sample. Control samples were tested using 3 lots of test strips and 10 meters for a total of 30 replicates per control sample. The differences in meter results between the test sample and the control sample were calculated. The table below summarizes the results. At the following concentrations, the difference between the test samples and control samples was $\leq \pm 10\%$.

Potential Interfering Substance	Highest Concentration Without Significant Interference, mg/dL
Acetaminophen	8
Ascorbic acid(Vitamin C)	5
Conjugated Bilirubin	90
Unconjugated Bilirubin	90
Cholesterol	500
Creatinine	30
Dopamine	2
EDTA	360
Galactose	900
Gentisic acid	5

Potential Interfering Substance	Highest Concentration Without Significant Interference, mg/dL
Glutathione	53
Hemoglobin	20,000
Heparin, IU/dL	8,000
Ibuprofen	50
Icodextrin	2,000
L-DOPA	10
Maltose	1,000
Methyl-DOPA	3
Salicylate	60
Sodium	460
Tolazamide	100
Tolbutamide	400
Triglycerides	2,000
Urate (uric acid)	10
Xylose	100
Mannitol	5,000
Sorbitol	1,000
Xylitol	1,000
Lactitol	1,000
Isomalt	1,000
Maltitol	1,000

The sponsor lists the following limitations in the SuperCheck Pro Blood Glucose Monitoring System User Guide and the SuperCheck Pro Test Strip Insert:

- Do not use this device while taking acetaminophen or acetaminophen containing drugs (such as certain cold and flu remedies or certain prescription drugs, when acetaminophen in your blood >8 mg/dL). You may receive incorrect results if you have recently taken any acetaminophen.
- If you are taking a high level of vitamin C (ascorbic acid level in your blood > 5 mg/dL), your blood glucose results may not be reliable. If you are unsure, ask your doctor.
- If you have a disease or condition that elevates your blood uric acid level (Uric acid level in your blood > 10 mg/dL) such as gout, your blood glucose results may not be accurate with the system. If you are unsure, ask your doctor.
- Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood can give falsely elevated results.

4. Assay Reportable Range:

   20 – 600 mg/dL glucose

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Traceability:

The system is traceable to NIST (National Institute of Standards and Technology) standard reference material NIST SRM #917c. A method comparison was performed using the candidate device and a YSI 2300 comparator method. The meter provides plasma-equivalent results.

Test Strip Stability:

Test strip (vials and individually wrapped pouches of strips) stability was assessed using real time stability studies. Protocols and acceptance criteria were reviewed and found acceptable to support the labeling claims that vialed test strips are stable for 180 days after first being opened, and that closed vials and individually wrapped pouches are stable for 30 months when stored between 39.2ºF to 104ºF (4ºC-40ºC) and 10-85% relative humidity.

6. Detection Limit:

Please refer to the linearity study above.

7. Assay Cut-Off:

Not applicable.

8. Accuracy (Instrument):

Not applicable.

9. Carry-Over:

Not applicable.

B. Comparison Studies:

1. Method Comparison with Predicate Device:

See lay-user performance study below.

2. Matrix Comparison:

Not applicable.

C. Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Lay-user Performance study:

A lay user performance study was conducted with a total of 350 participants to assess the performance of the SuperCheck Pro Blood Glucose Monitoring System. The participants were responsible for obtaining their own capillary sample and performing a blood glucose test using only the instructions from the product labeling in English. Results were analyzed by comparing blood glucose results from capillary whole blood on the SuperCheck Pro Blood Glucose Monitoring System obtained by the lay user against results obtained on the YSI 2300 comparator method. The glucose concentrations of the samples ranged from 43.3 to 456 mg/dL, which included 15 native samples with glucose levels < 80 mg/dL and 50 samples with glucose levels > 250 mg/dL, as measured by the YSI 2300 comparator method. The results are summarized in the tables below:

Fingertip vs. Plasma YSI

For all glucose concentrations

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
236/350 (67.4%)	328/350 (93.7%)	348/350 (99.4%)	350/350 (100%)

For glucose concentrations <75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
12/13(92.3%)	13/13(100%)	13/13(100%)	13/13(100%)

For glucose concentrations ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
224/337(66.5%)	313/337(92.9%)	335/337(99.4%)	337/337(100%)

Palm vs. Plasma YSI

For all glucose concentrations

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
236/350 (67.4%)	323/350 (92.3%)	347/350 (99.1%)	350/350 (100%)

For glucose concentrations <75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
7/13(53.8%)	11/13(84.6%)	13/13(100%)	13/13(100%)

For glucose concentrations ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
229/337(68%)	312/337(92.6%)	334/337(99.1%)	337/337(100%)

Forearm vs. Plasma YSI

For all glucose concentrations

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
239/350 (68.3%)	330/350 (94.3%)	349/350 (99.7%)	350/350 (100%)

For glucose concentrations <75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
8/13(61.5%)	13/13(100%)	13/13(100%)	13/13(100%)

For glucose concentrations ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
231/337(68.5%)	317/337(94.1%)	336/337(99.7%)	337/337(100%)

Upper arm vs. Plasma YSI

For all glucose concentrations

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
220/350 (62.9%)	320/350 (91.4%)	348/350 (99.4%)	350/350 (100%)

For glucose concentrations <75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
9/13(69.2%)	11/13(84.6%)	13/13(100%)	13/13(100%)

For glucose concentrations ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
211/337(62.6%)	309/337(91.7%)	335/337(99.4%)	337/337(100%)

Calf vs. Plasma YSI

For all glucose concentrations

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
217/350 (62%)	328/350 (93.7%)	347/350 (99.1%)	350/350 (100%)

For glucose concentrations <75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
8/13(61.5%)	12/13(92.3%)	13/13(100%)	13/13(100%)

For glucose concentrations ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
209/337(62%)	316/337(93.8%)	334/337(99.1%)	337/337(100%)

Thigh vs. Plasma YSI

For all glucose concentrations

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
221/350 (63.1%)	325/350 (92.9%)	349/350 (99.7%)	350/350 (100%)

For glucose concentrations <75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
8/13(61.5%)	13/13(100%)	13/13(100%)	13/13(100%)

For glucose concentrations ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
215/337(63.8%)	312/337(92.6%)	336/337(99.7%)	337/337(100%)

Accuracy at Extreme Glucose Study:

An accuracy study was performed to evaluate the performance of the SuperCheck Pro Blood Glucose Monitoring System in the extreme lower and upper ends of the claimed glucose measuring range using capillary whole blood samples from 10 volunteers. Each of the ten volunteer capillary whole blood samples was used to prepare 10 samples for a total of 100 samples. Fifty (50) samples were altered by glycolysis to achieve glucose concentrations below 80 mg/dL and the other 50 samples were spiked to achieve glucose concentrations greater than 250 mg/dL. The 100 samples were tested using 3 test strip lots, and the glucose results using the candidate device compared to results obtained on the YSI 2300 analyzer are summarized below:

Extreme glucose study results for glucose concentrations < 80 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
24/50(48%)	42/50(84%)	49/50(98%)	50/50(100%)

Extreme glucose study results for glucose concentrations > 250 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
31/50(62%)	49/50(98%)	50/50(100 %)	50/50(100 %)

Usability:

At the end of the lay user performance study, each participant was asked to complete a usability questionnaire regarding ease of understanding of information in the user manual and the ease of use when performing a blood glucose test with the SuperCheck Pro Blood Glucose Monitoring System. From the sponsor's analysis of the questionnaire responses, the participants were satisfied with the ease of operation following the instructions for use in the labeling and with their overall ability to conduct testing with the candidate device.

Readability:

A Flesch-Kincaid readability assessment was conducted on the user manual and the test strip insert and demonstrated that the overall readability was at an 8th grade level or lower.

D. Clinical Cut-Off:

Not Applicable.

E. Expected Values/Reference Range:

The following statements regarding expected glucose values for people without diabetes are included in the device labeling:

"The fasting blood glucose range for a nondiabetic person is less than 100 mg/dL and less than 140 mg/dL up to 2 hours after meals. These are expected values for people without diabetes. Users should cooperate with their healthcare professional to determine their target blood glucose values."

Reference: *Diabetes Care 2020;43 (Suppl. 1): S14-S31, American Diabetes Association.*

F. Other Supportive Instrument Performance Characteristics Data:

1. Hematocrit:

To evaluate the effect of hematocrit on the SuperCheck Pro Blood Glucose Monitoring System, venous blood samples were adjusted to hematocrit levels of 20%, 25%, 30%, 35%, 42%, 45%, 50%, 55%, 60%. Each sample was then adjusted to achieve 5 glucose concentrations within the following ranges (30-50, 51-110, 111-150, 151-250, and 251-400 mg/dL). Each blood sample at each condition was tested using 10 SuperCheck Pro Blood Glucose Meters using 3 lots of test strips, and was also tested on the YSI 2300 comparator method. The values for each level of glucose were compared to results using the YSI 2300 comparator method, and to the normal hematocrit sample. The results support the claimed hematocrit range of 20%-60% for the SuperCheck Pro Blood Glucose Monitoring System.

2. Sample Volume:

A minimum sample volume study was performed to verify the minimum test strip sample volume requirement and the test strip fill error function established for the candidate device. Three lots of test strips on 10 meters were tested using venous blood samples at 3 concentrations (50-65, 100-120, and 200-250 mg/dL) at each condition. Blood at each concentration was applied to strips at 4 target sample volumes of 0.3, 0.4, 0.5, and 0.6 µL. The study results supported the minimum sample volume claim of 0.5 µL for the system. The meter either displays an error message or does not start the test if not enough blood is added to the test strip. This feature was validated and was shown to function as intended.

3. Altitude Study:

To evaluate the effect of altitude on the SuperCheck Pro Blood Glucose Monitoring System, meters were tested in mountains at elevations of 298, 4,790, and 11,161 feet above sea level using whole venous blood samples adjusted to 5 concentration levels of glucose ranging from 30-400 mg/dL. At each elevation, each glucose sample was tested using 10 meters and 3 lots of test strips for a total 30 replicates. The results obtained on the candidate device were

compared with the results obtained with the YSI 2300 comparator method. The results support the claim that glucose measurement performance of the SuperCheck Pro Blood Glucose Monitoring System is maintained at altitudes up to 11,161 feet (3,402 meters).

4. Operating Conditions:

The effect of temperature and relative humidity on the SuperCheck Pro Blood Glucose Monitoring System was evaluated using venous whole blood samples adjusted to approximately 3 glucose concentration ranges: 30-50, 111-150, and 251-400 mg/dL. Testing was conducted under the following temperature and relative humidity (RH) combinations: 46.4°F (8°C) at 5% and 90% RH; 50°F (10°C) at 10% and 85% RH; 104°F (40°C) at 10% and 85% RH; 107.6°F (42°C) at 5 and 90% RH; 23°C at 50% RH. Each glucose concentration at each condition was tested using 10 meters and 3 lots of test strips for a total of 30 replicates. Values were compared to results from the YSI 2300 comparator method. The study results support the operating conditions claim of 50-104°F (10-40°C) with relative humidity of 10% to 85%.

5. **Infection Control Studies:**

The SuperCheck Pro Blood Glucose Monitoring System is intended for single-patient use only. Disinfection efficacy studies were performed on the external meter materials by an outside commercial testing laboratory to demonstrate complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, the PDI Super Sani-Cloth Germicidal Disposable Wipe (EPA Reg. No. 9480-4).

Robustness studies were also performed by the sponsor to demonstrate that there was no change in performance or change in the external materials of the meter after 520 cleaning and disinfection cycles with the PDI Super Sani-Cloth Germicidal Disposable Wipes. The robustness studies were designed to simulate single-patient use with cleaning and disinfection twice per week for five years.

Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6. Flex Studies:

Flex studies were performed demonstrating that the SuperCheck Pro Blood Glucose Monitoring System is robust to sample perturbation, testing with used test strips, intermittent sampling, testing outside of the specified operation condition range, shipping, drop and vibration.

7. Electromagnetic Compatibility (EMC) Testing:

The sponsor provided documentation certifying that acceptable electrical safety and EMC testing had been performed and the system was found to be compliant.

8. **Test Strip Lot Release**

The test strip lot release protocols and criteria were reviewed and found to be acceptable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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