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

A. 510(k) Number:

k173140

B. Purpose for Submission:

New devices

C. Measurand:

Glucose in capillary whole blood obtained from the fingertip

D. Type of Test:

Quantitative, amperometric method, glucose oxidase

E. Applicant:

VivaChek Laboratories, Inc.

F. Proprietary and Established Names:

VivaChek Ino Smart Blood Glucose Monitoring System
VivaChek Ino Sync Blood Glucose Monitoring System
VivaChek Ino Sound Blood Glucose Monitoring System
VivaChek Ino Plus Blood Glucose Monitoring System
VivaChek Ino Sound Simple Blood Glucose Monitoring System
VivaChek Ino Sound Bright Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345, Glucose test system

2. Classification:

   Class II

3. Product code:

   NBW, System, Test, Blood Glucose, Over The Counter

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use below

2. Indication(s) for use:

   VivaChek Ino Smart Blood Glucose Monitoring System
   VivaChek Ino Smart Blood Glucose Monitoring System is comprised of the VivaChek Ino Smart Blood Glucose Meter (VGM04) and the VivaChek Ino Blood Glucose Test Strips (VGS01). The VivaChek Ino Smart Blood Glucose Monitoring System is intended to quantitatively measure the glucose concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for use by persons with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for neonatal use or for the diagnosis of or screening for diabetes. This system is intended for self-testing outside the body (in vitro diagnostic use), and should only be used by a single person and should not be shared.

   VivaChek Ino Sync Blood Glucose Monitoring System
   VivaChek Ino Sync Blood Glucose Monitoring System is comprised of the VivaChek Ino Sync Blood Glucose Meter (VGM05) and the VivaChek Ino Blood Glucose Test Strips (VGS01). The VivaChek Ino Sync Blood Glucose Monitoring System is intended to quantitatively measure the glucose concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for use by persons with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for neonatal use or for the diagnosis of or screening for diabetes. This system is intended for self-testing outside the body (in vitro diagnostic use), and should only be used by a single person and should not be shared.

   VivaChek Ino Sound Blood Glucose Monitoring System
   VivaChek Ino Sound Blood Glucose Monitoring System is comprised of the VivaChek Ino Sound Blood Glucose Meter (VGM09) and the VivaChek Ino Blood Glucose Test Strips (VGS01). The VivaChek Ino Sound Blood Glucose Monitoring System is intended to quantitatively measure the glucose concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for use by persons with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for neonatal use or for the diagnosis of or screening for diabetes. This system is intended for self-

testing outside the body (in vitro diagnostic use), and should only be used by a single person and should not be shared.

VivaChek Ino Plus Blood Glucose Monitoring System
VivaChek Ino Plus Blood Glucose Monitoring System is comprised of the VivaChek Ino Plus Blood Glucose Meter (VGM22) and the VivaChek Ino Blood Glucose Test Strips (VGS01). The VivaChek Ino Plus Blood Glucose Monitoring System is intended to quantitatively measure the glucose concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for use by persons with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for neonatal use or for the diagnosis of or screening for diabetes. This system is intended for self-testing outside the body (in vitro diagnostic use), and should only be used by a single person and should not be shared.

VivaChek Ino Sound Simple Blood Glucose Monitoring System
VivaChek Ino Sound Simple Blood Glucose Monitoring System is comprised of the VivaChek Ino Sound Simple Blood Glucose Meter (VGM26) and the VivaChek Ino Blood Glucose Test Strips (VGS01). The VivaChek Ino Sound Simple Blood Glucose Monitoring System is intended to quantitatively measure the glucose concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for use by persons with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for neonatal use or for the diagnosis of or screening for diabetes. This system is intended for self-testing outside the body (in vitro diagnostic use), and should only be used by a single person and should not be shared.

VivaChek Ino Sound Bright Blood Glucose Monitoring System
VivaChek Ino Sound Bright Blood Glucose Monitoring System is comprised of the VivaChek Ino Sound Bright Blood Glucose Meter (VGM27) and the VivaChek Ino Blood Glucose Test Strips (VGS01). The VivaChek Ino Sound Bright Blood Glucose Monitoring System is intended to quantitatively measure the glucose concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for use by persons with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for neonatal use or for the diagnosis of or screening for diabetes. This system is intended for self-testing outside the body (in vitro diagnostic use), and should only be used by a single person and should not be shared.

3. Special conditions for use statement(s):

- Very high (above 70%) and very low (below 20%) hematocrit levels can cause false results. Talk to your health care professional to find out your hematocrit level.
- Not for use in hypotensive individuals
- Critically ill patients should not be tested with this system.
- Not for use on patients in shock, or with severe dehydration or from patients in a hyperosmolar state (with or without ketosis).
- Not for neonatal use.
- Not for screening or diagnosis of diabetes mellitus.

- Do not use at altitudes above 13,123ft (4000 meters) above sea level.
- For single-patient use only
- This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. 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.

4. Special instrument requirements:

VivaChek Ino Smart Blood Glucose Meter (VGM04)
VivaChek Ino Sync Blood Glucose Meter (VGM05)
VivaChek Ino Sound Blood Glucose Meter (VGM09)
VivaChek Ino Plus Blood Glucose Meter (VGM22)
VivaChek Ino Sound Simple Blood Glucose Meter (VGM26)
VivaChek Ino Sound Bright Blood Glucose Meter (VGM27)

I. Device Description:

The six systems in this submission, the VivaChek Ino Smart, the VivaChek Ino Sync, the VivaChek Ino Sound, the VivaChek Ino Plus, the VivaChek Ino Sound Simple, and the VivaChek Ino Sound Bright Blood Glucose Monitoring Systems are intended to quantitatively measure the glucose concentration in fresh capillary whole blood. The glucose measurement is achieved by using the amperometric detection method. The test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the test strip. The blood sample is pulled into the tip of the test strip through capillary action. Glucose in the sample reacts with glucose enzyme and the mediator. Electrons are generated, producing a current that is positive correlation to the glucose concentration in the sample. After the reaction time, the glucose concentration in the sample is displayed. The meter is calibrated to display plasma-like concentration results.

The same test strips, the VivaChek Ino Blood Glucose Test Strips (VGS01) are used with each of the meters in this submission, the VivaChek Ino Smart (VGM04), VivaChek Ino Sync (VGM05), VivaChek Ino Sound (VGM09), VivaChek Ino Plus (VGM22), VivaChek Ino Sound Simple (VGM26), and VivaChek Ino Sound Bright (VGM27) Blood Glucose Meters to measure the glucose level in fresh capillary whole blood. VivaChek Control Solutions are aqueous solutions containing glucose and are available at three levels (level 1, level 2 and level 3) and are compatible for use with each system.

All of the devices in this 510(k) submission employ the same device technology and have the same intended use. The devices differ in minor design features and certain user functions. For example, the VGM04, VGM05, VGM09, and VGM22 meter models contain Bluetooth functionality for transferring glucose results to a compatible mobile device, and the VGM09, VGM26, and VGM27 meter models contain a talking functionality. Other

features that differ between meters are minor features such as presence or absence of a backlight, strip ejector port, or rechargeable batteries.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   VivaChek Ino Blood Glucose Monitoring System

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

   k160179

3. Comparison with predicate:

Item	Candidate Devices (k173140)	Predicate Device (k160179)
Indications for use	Quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip as an aid to monitor the effectiveness of diabetes control	Same
Detection method	Amperometric	Same
Enzyme	Glucose oxidase	Same
Measuring range	20-600 mg/dL	Same
HCT range	20-70%	Same
Sample volume	0.8µL	Same
Operating temperature	5–45ºC (41–113ºF)	Same
Operating relative humidity	10-90%	Same
Sample type	Capillary whole blood from fingertip	Capillary whole blood from fingertip, palm and forearm
Altitude	13,123 feet	9,777 feet

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

Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use, Guidance for Industry and Food and Drug Administration Staff. October 11, 2016.

L. Test Principle:

The VivaChek Ino Smart Blood Glucose Monitoring System, VivaChek Ino Sync Blood Glucose Monitoring System, VivaChek Ino Sound Blood Glucose Monitoring System, VivaChek Ino Plus Blood Glucose Monitoring System, VivaChek Ino Sound Simple Blood Glucose Monitoring System, and VivaChek Ino Sound Bright Blood Glucose Monitoring System are systems for the quantitative detection of glucose in fresh capillary whole blood from the fingertip. Amperometric technology is used for the detection of glucose from testing the strip (with whole blood sample) on the meter. Reagent consisting of glucose oxidase and mediator is deposited onto the reaction cell section of the test strip with printed electrodes. When a drop of whole blood sample is applied to the reaction cell on the test strip, glucose in the blood sample reacts in the presence of glucose oxidase and mediator, and the reaction yields electrons. Thus, a current signal is produced from the reaction and detected by the meter. The detected current signal is then calculated by the meter, and glucose concentration reading is then displayed on the meter display.

M. Performance Characteristics (if/when applicable):

Unless otherwise noted, the analytical studies detailed below were performed with the VivaChek Ino Smart Blood Glucose Monitoring System. As the only differences between the six meters in this submission are minor design features, as described above in Device Description (Section I), the analytical studies performed with the VivaChek Ino Smart Blood Glucose Monitoring System are representative of the performance for all devices in this 510(k) submission.

1. Analytical performance:

   a. Precision/Reproducibility:

   Repeatability (within-run precision):

   The sponsor performed repeatability (within-day) precision studies using venous whole blood adjusted to 5 different glucose concentration levels (30 to 50, 51 to 110, 111 to 150, 151 to 250, and 251 to 400 mg/dL). Each glucose concentration level was analyzed in replicates of 10, with 3 test strip lots, and 10 meters, for a total of 300 tests per glucose level for each meter. Results are summarized below:

Glucose Level (mg/dL)	Strip Lot	n	Average Glucose (mg/dL)	SD (mg/dL)	CV (%)
30-50	1	100	49.5	2.3	4.6
	2	100	49.5	2.2	4.4
	3	100	49.5	2.2	4.5
51-110	1	100	78.1	2.5	3.2
	2	100	78.1	2.7	3.4
	3	100	78.1	2.6	3.3
111-150	1	100	133.5	4.0	3.0
	2	100	133.5	3.7	2.8
	3	100	133.5	3.8	2.8
151-250	1	100	200.7	5.8	2.9
	2	100	200.7	5.7	2.9
	3	100	200.7	5.4	2.7
251-400	1	100	357.5	10.3	2.8
	2	100	357.5	10.5	2.8
	3	100	357.5	10.2	2.8

Intermediate Precision:

Intermediate (day-to-day) precision was evaluated using 3 levels of glucose control solutions over 10 days with 3 test strip lots. For each level, on each day, 10 meters were used for testing, with 1 replicate collected per meter for a total of 10 replicates per day for each glucose level. Results are summarized below:

Glucose Level (mg/dL)	Strip Lot	n	Average Glucose (mg/dL)	SD (mg/dL)	CV (%)
Level 1	1	100	50.5	2.4	4.8
	2	100	50.6	2.4	4.8
	3	100	50.5	2.4	4.6
Level 2	1	100	117.5	3.2	2.7
	2	100	119.1	2.8	2.4
	3	100	118.1	2.8	2.3
Level 3	1	100	360.0	8.5	2.4
	2	100	359.6	9.4	2.6
	3	100	358.2	9.1	2.5

b. Linearity/assay reportable range:

Linearity testing was performed using venous whole blood samples. Samples with the following glucose concentrations were prepared and confirmed by the laboratory comparator method YSI 2300: 21.7, 77.7, 135.7, 196.3, 250.8, 308.6, 368.1, 425.9,

481.0, 541.6, 595.0 mg/dL. Each sample was measured in replicates of four using each of three lots of test strips and the mean was used in the regression analysis. The regression analysis results are summarized in the table below:

Lot	Slope	y-intercept	R^2
1	0.9983	0.0150	0.9986
2	0.9852	2.4035	0.9974
3	1.0052	-2.2806	0.9982

The results of the study support the sponsor's claimed glucose measuring range of 20 – 600 mg/dL. If a sample is less than 20 mg/dL glucose, the result is flagged by the meter as LO. If a sample result exceeds 600 mg/dL glucose, the result is flagged by the meter as HI. The LO and HI functions were validated and demonstrated to function as intended.

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

Traceability:

The system is traceable to NIST SRM #917b glucose reference material. A method comparison was performed using the candidate device and YSI 2300 as the reference method. The meter provides plasma-equivalent results.

Test Strip Stability:

Test strip stability was assessed using accelerated and real time stability studies. Protocols and acceptance criteria were reviewed and found acceptable. The labeling includes claims that the VivaChek Ino Test Strips are stable for 4 months after opening and 24 months unopened when stored between of 36ºF to 86ºF (2ºC-30ºC) and 10-90% relative humidity.

d. *Detection limit:*

The reportable range for the VivaChek Blood Glucose Monitoring System is 20 to 600 mg/dL supported by the linearity assay study above (M.1.b).

e. *Analytical specificity:*

To assess potential interferences, the sponsor used venous whole blood samples adjusted to 3 glucose concentration ranges: 50-70, 110-130, 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. The % difference between the test sample and the control sample was calculated using mean of 10 replicates for each of the 3 strip lots tested. The compounds at the concentrations listed below did not have significant interference (defined by the sponsor as average bias between spiked and control sample glucose results within ±

10% with glucose >100 mg/dL and within 10 mg/dL with glucose <100 mg/dL). The highest concentrations at which no significant interference was observed are presented in the following table:

Substance	Highest Concentration tested with no observed interference
Acetaminophen	20 mg/dL
Ascorbic acid	3 mg/dL
Bilirubin	40 mg/dL
Cholesterol	500 mg/dL
Creatinine	10 mg/dL
Dopamine	20 mg/dL
Galactose	15 mg/dL
Gentisic acid	27.8 mg/dL
Glutathione	92 mg/dL
Hemoglobin	20 g/dL
Ibuprofen	50 mg/dL
L-Dopa	0.5 mg/dL
Maltose	225 mg/dL
Methyldopa	10.5 mg/dL
Salicylic acid	60 mg/dL
Sodium	350 mg/dL
Tolbutamide	64 mg/dL
Tolazamide	10 mg/dL
Triglycerides	1500 mg/dL
Uric acid	24 mg/dL
Xylose	200 mg/dL
Mannitol	0.09 mg/dL
Sorbitol	0.09 mg/dL
Lactose	25 mg/dL
Tetracycline	1.5 mg/dL

The sponsor lists the following limitations in the User Manual and the Test Strip Insert:

- If you are taking vitamin C (ascorbic acid in your blood > 3 mg/dL) then your glucose results using this meter may not be reliable.
- The VivaChek Ino Blood Glucose Monitoring System should not be used following xylose absorption procedures.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable. See section M.3.c. below for performance in the hands of the intended user.

b. Matrix comparison:

Not applicable

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):

User Performance Study:

To assess the performance of the VivaChek Ino Blood Glucose Monitoring Systems in the hands of the intended users, the sponsor performed four independent studies that each included a minimum of 350 lay users with the VivaChek Ino Smart (VGM04), VivaChek Ino Sound (VGM09), VivaChek Ino Plus (VGM22), and VivaChek Ino Sound Simple (VGM26) Blood Glucose Meters (see Section I Device Description for a description of the minor differences between each meter). Each study included lay users that were provided with the device labeling, collected their own fingerstick sample, and obtained results on a VivaChek Ino meter. After the tests were completed by the lay user, additional blood samples were collected from each subject by a professional for testing with the comparator method, YSI 2300. There were no significant differences demonstrated in performance between the four lay user studies completed. As representative performance, the results from the most complex system (e.g. presence of talking feature, bluetooth function, backlight, strip ejector etc.), the VivaChek Ino Sound Blood Glucose Monitoring System (VGM09), are summarized in the tables below:

VivaChek Ino Sound Blood Glucose Monitoring System (VGM09)

For glucose concentrations <75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 20 mg/dL
49/65 (75.4%)	64/65 (98.5%)	64/65 (98.5%)	65/65 (100%)

For glucose concentrations >75 mg/dL			
Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
209/290 (72.1.0%)	281/290 (96.9%)	290/290 (100%)	290/290 (100%)

All glucose concentrations			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
243/355 (68.5%)	337/355 (94.9%)	354/355 (99.7%)	355/355 (100%)

Results of linear regression analysis:

$y= 1.0031x - 0.7024$; $R^2 = 0.9950$

Accuracy at Extreme Glucose Study:

To assess the performance of the VivaChek Ino Blood Glucose Monitoring Systems at extreme glucose concentrations, a study was conducted using blood from 105 study participants where blood was either aged to lower glucose concentrations or spiked to raise glucose concentration. The results were compared to the YSI 2300 comparator method. Results demonstrate that the meter has acceptable accuracy at extreme glucose values.

For glucose concentrations < 80 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
48/53 (90.6%)	53/53 (100%)	53/53 (100%)

For glucose concentrations >250 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
35/52 (67.3%)	52/52 (100%)	52/52 (100%)	52/52 (100%)

Usability/Readability:

The study participants were 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. The study demonstrated that users of the device were able to understand and follow the instructions provided in the labeling to perform tasks involved in blood glucose testing.

Flesch-Kincaid readability assessment was conducted on all labeling and demonstrated that the user manuals are written at an 8th grade level or below.

4. Clinical cut-off**:**

Not applicable.

5. Expected values/Reference range:

The sponsor includes the following expected glucose values for people without diabetes in the device labeling.

Time of day	**Glucose Range**
Fasting and before meals	<100 mg/dL
2 hours after meals	<140 mg/dL

Source: American Diabetes Association (Standards of Medical Care in Diabetes – 2018. Diabetes Care, January 2018, vol. 41, Supplement 1, S13-S27).

N. Instrument Name:

VivaChek Ino Smart Blood Glucose Meter (VGM04)
VivaChek Ino Sync Blood Glucose Meter (VGM05)
VivaChek Ino Sound Blood Glucose Meter (VGM09)
VivaChek Ino Plus Blood Glucose Meter (VGM22)
VivaChek Ino Sound Simple Blood Glucose Meter (VGM26)
VivaChek Ino Sound Bright Blood Glucose Meter (VGM27)

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 ____X____ or No _____

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

Yes ____X____ or No _____

The VivaChek Ino Smart, VivaChek Ino Sync, VivaChek Ino Sound, and VivaChek Ino Plus Blood Glucose Monitoring System have the ability to transmit data to a mobile device via Bluetooth. The VivaChek Ino Sound Simple and VivaChek Ino Sound Bright Blood Glucose Monitoring Systems do not have the ability to transmit data to a

computer, webserver, or mobile device.

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:

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

4. Specimen Sampling and Handling:

   The system is intended to be used with capillary whole blood from the finger. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   Calibration is automatic. There is no user input for coding.

6. Quality Control:

   VivaChek Control Solutions are aqueous solutions containing glucose and are available at three levels (level 1, level 2 and level 3). Instructions on how to order the control solutions are included in the user manual. The control solution readings are not included in the average of the patient results. An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. Hematocrit Study:
   To evaluate the effect of hematocrit on the VivaChek Ino Blood Glucose Monitoring System, venous blood samples with hematocrit levels of 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, and 70% were tested at 5 glucose concentrations (50, 90, 130, 200, and 330 mg/dL). Each sample was tested in replicates of 10 test strips per strip lot, with a total of 3 lots of testes strips tested. Results from the meter were compared to results obtained using a laboratory-based comparator method (YSI 2300). The evaluation of bias relative to the comparator method demonstrated acceptable performance to support the claimed hematocrit range of 20-70%.

2. Altitude Study:
   To evaluate the effect of altitude on the VivaChek Ino Blood Glucose Monitoring System, meters were tested at sea level and 13,123 feet. The evaluation included 3 test strip lots and the glucose range tested was 52 to 538 mg/dL. Results at each altitude were compared to the comparator method, YSI 2300. Results demonstrated that altitudes up to 13,123 feet above sea level have no significant effect on blood glucose measurements.

3. Sample Volume Study:
   The sponsor performed a study to support the claimed minimum sample volume for the VivaChek Ino Blood Glucose Monitoring System. Venous whole blood samples were tested at 0.6, 0.7, and 0.8 µL at thee glucose levels (60, 110, and 230 mg/dL) as established by the YSI 2300 comparator method. Each sample was tested in duplicate on two meters using 3 test strip lots. Results support the claimed minimum sample volume of 0.8µL. The sponsor provided validation studies demonstrating that with blood volumes below 0.8 µL, the insufficient sample volume error message functioned as intended.

4. Operating Conditions Study:
   The sponsor performed temperature and humidity studies using venous blood samples with three glucose levels (60-70, 100-120, and 300-400 mg/dL). Temperatures ranging from 41°F - 113°F (5-45°C) and relative humidity from 10% to 90% were tested. Meter results were compared to the YSI 2300 comparator analyzer. Four temperature and humidity combinations were tested including low temperature/low humidity, low temperature/high humidity, high temperature/low humidity and high temperature/high humidity. The results support the claims in the labeling that the system can be used in conditions of 41°F - 113°F (5-45°C) with relative humidity of 10 to 90%.

5. Flex Studies:
   Intermittent sampling, sample perturbation, testing with used test strips, drop/shock testing, and vibration testing was completed. The testing performed demonstrated that the VivaChek Ino Blood Glucose Monitoring Systems are robust to intermittent sampling, sample perturbation, drop/shock, and vibration, and that an error message is returned to the user if a used test strip is inserted into the meter.

6. EMC Testing:
   The sponsor provided appropriate documentation certifying that acceptable electromagnetic testing (EMC) had been performed for each device in this 510(k) submission and that they were compliant.

7. Infection Control Studies:
   The six VivaChek Ino systems in this submission are intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meters by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Clorox Germicidal Wipes, 0.55% sodium hypochlorite (EPA Registration # 67619-12). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 608 cleanings and disinfection cycles with the Clorox Germicidal

Wipes. The robustness studies were designed to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

8. Test Strip Lot Release Protocol:
   The test strip lot release protocol and acceptance criteria were reviewed and found to be acceptable.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

R. Conclusion:

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