

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

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

k131727

**B. Purpose for Submission:**

New device

**C. Measurand:**

Capillary whole blood glucose from the fingertip, forearm, upper arm, palm, thigh or calf

**D. Type of Test:**

Quantitative, amperometric, electrochemical biosensor, Glucose Dehydrogenase (FAD-GDH)

**E. Applicant:**

CERAGEM Medisys Inc.

**F. Proprietary and Established Names:**

CERA-CHEK 1070 Blood Glucose Monitoring System

**G. Regulatory Information:**

Regulation Section	Classification	Product Code	Panel
21 CFR § 862.1345	Class II	LFR, glucose dehydrogenase, glucose	Clinical Chemistry (75)
21 CFR § 862.1345	Class II	NBW, system, test, blood glucose, over the counter	Clinical Chemistry (75)
21 CFR § 862.1660	Class I, reserved	JJX, single (specified) analyte controls (assayed and unassayed)	Clinical Chemistry (75)
21 CFR § 862.2100	Class I, reserved	JQP, calculator/data processing module for clinical use	Clinical Chemistry (75)

**H. Intended Use:**

1. Intended use(s):

See indication(s) for use below.

2. Indication(s) for use:

The CERA-CHEK 1070 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip., forearm, upper arm, palm, thigh or calf. The CERA-CHEK 1070 Blood Glucose Monitoring System is intended to be used by a single person and should

not be shared. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The CERA-CHEK 1070 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The CERA-CHEK 1070 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The CERA-CHEK 1070 Blood Glucose Test Strips are for use with the CERA-CHEK 1070 Blood Glucose Test Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, forearm, upper arm, palm, thigh or calf.

The CERA-CHEK 1070 Control Solution is for use with the CERA-CHEK 1070 Blood Glucose Test Meter and Test strips as a quality control check to verify that the meter and test strips are working together properly and that the test is performing correctly.

The CERA-CHEK Diabetes Management Software is PC-based software intended for use in home and professional settings to help people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose results for effective diabetes management. It is intended for use as an accessory to compatible CERAGEM MEDISYS blood glucose monitoring systems. CERA-CHEK Diabetes Management Software's language is English.

3. Special conditions for use statement(s):

For over-the-counter use.

Not for screening for or diagnosis of diabetes mellitus.

Not for neonatal use.

Not for use on critically ill patients, patients in shock, dehydrated patients or hyperosmolar patients.

For single patient use only and should not be shared.

Alternative site testing (AST) should only be done during steady-state times (when glucose is not changing rapidly).

AST measurements should not be used to calibrate CGMs.

AST measurements should not be used in insulin dose calculations.

4. Special instrument requirements:

CERA-CHEK 1070 Blood Glucose Meter

**I. Device Description:**

The CERA-CHEK 1070 Blood Glucose Monitoring System consists of the CERA-CHEK 1070 Glucose Meter, CERA-CHEK 1070 Blood Glucose Test Strips with Code Key, CERA-CHEK 1070 Control Solution 1 and Control Solution 2, a Lancing device and CERACHEK Diabetes Management Software and cable needed for installing the software on the PC and for transmitting data from meter.. Control Solution 1 and Control Solution 2 are required but not included with the meter. Control Solution 1 and Control Solution 2 are always provided as a set. CERA-CHEK Diabetes Management Software and cable are required but not included with the meter. CERA-CHEK Diabetes Management Software and cable are always provided as a set.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Ascensia® CONTOUR® Blood Glucose Monitoring System

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

k062058

3. Comparison with predicate:

<b>Similarities and Differences</b>		
<b>Item</b>	<b>Candidate Device (k131727) CERA-CHEK 1070 Blood Glucose Monitoring System</b>	<b>Predicate (k062058) Ascensia CONTOUR Blood Glucose Monitoring System</b>
Enzyme	Glucose Dehydrogenase (FAD-GDH)	Same
Detection Method	Amperometry	Same
Test Time	5 seconds	Same
Measuring Range	20 - 600 mg/dL	10 - 600 mg/dL
Sample type	capillary whole blood	capillary, venous, and arterial whole blood samples and neonatal blood samples.
Testing Site	fingertip, forearm, upper arm, palm, thigh or calf.	fingertip, palm, forearm, and in the case of neonates, the heel.
Sample Volume	0.5 µL	0.6 µL
Coding	Code key required	No coding
Quality Control	2 levels	3 levels
Hematocrit Range	10 – 70%	20 - 60%
Operating Humidity Range	10 – 85%	10 – 93%
Operating Temperature Range	50 – 104°F 10-40°C	41 – 113°F 5-45°C
Memory	1000 results with date and time	480 results with date and time
Dimension/Weight	94mm(H) x 53.6mm(W) x 14.9mm(T), 35g	77mm(H) x 57mm(W) x 19mm(T), 47.5g
Power (Battery)	One 3-volt lithium battery (CR2032)	Two 3-volt lithium batteries (DL2032 or CR2032)

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

1. ISO 15197: 2003: *In vitro* diagnostic test systems – Requirements for blood- glucose monitoring systems for self-testing in managing diabetes mellitus
2. ISO 14971: 2007: Medical devices – application of risk management to medical devices.
3. EN 13612:2002: Performance evaluation of in vitro diagnostic medical devices

4. EN 13640: 2002: Stability testing of in vitro diagnostic medical devices
5. EN 61010-2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
6. IEC 61010-1:2001: Safety requirements for electrical equipment for measurement, control, and laboratory use
7. CLSI EP5-A: Evaluation of precision performance of clinical chemistry devices
8. CLSI EP6-A: Evaluation of the linearity of quantitative measurement procedures: a statistical approach
9. CLSI EP7-A: Interference testing in clinical chemistry
10. CLSI EP9-A: Method comparison and bias estimation using patient samples
11. FDA guidance: Review criteria for assessment of portable blood glucose monitoring in vitro diagnostic devices using glucose oxidase, dehydrogenase, or hexokinase methodology
12. Code of Federal Regulations title 21 section 809.10: Labeling for in vitro diagnostic products

**L. Test Principle:**

The test is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the test strip. The test meter measures the current and displays the corresponding blood glucose levels. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

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

1. Analytical performance:

a. Precision/Reproducibility:

Within-run precision was evaluated by analyzing venous whole blood samples spiked to five different glucose concentrations. The hematocrit of all samples was between 35 and 50%. Five different lot numbers of test strips and ten meters were used in the study and each of the samples was measured ten times per lot of test strip per meter for a total of 100 measurements per glucose concentration. The samples were analyzed by one operator in one day.

Strip Lot	Concentration of glucose (mg/dL)	N	Mean (mg/dL)	SD (mg/dL)	CV%
Lot 1	44	20	44.9	2.5	5.6
	96	20	98.5	3.0	3.1
	127	20	129.8	3.3	2.6
	226	20	229.1	6.8	3.0
	323	20	325.0	8.0	2.5
Lot 2	44	20	44.9	1.7	3.7
	96	20	96.7	3.1	3.2
	127	20	127.6	4.4	3.5
	226	20	231.0	6.7	2.9
	323	20	327.6	7.3	2.2
Lot 3	44	20	43.9	2.2	5.0
	96	20	98.1	2.7	2.8

	127	20	130.8	3.2	2.4
	226	20	225.8	5.4	2.4
	323	20	326.6	8.8	2.7
Lot 4	44	20	46.6	2.3	4.9
	96	20	95.4	2.6	2.7
	127	20	126.3	3.5	2.7
	226	20	225.8	6.5	2.9
	323	20	325.2	7.2	2.2
Lot 5	44	20	45.9	2.2	4.9
	96	20	99.2	2.5	2.5
	127	20	130.9	4.2	3.2
	226	20	229.7	7.7	3.3
	323	20	326.2	5.1	1.6

Day to day precision was evaluated by analyzing three levels of control samples. Three lots of test strips and ten meters were used in the study. Each control sample was measured once per day over twenty days using each of the ten meters and each lot of the test strips. In total, 600 measurements were taken for each of the three control samples. Results are summarized below:

Strip Lot	Concentration of glucose (mg/dL)	N	Mean (mg/dL)	SD (mg/dL)	CV%
Lot 1	43	200	43.4	1.9	4.4
	108	200	110.2	3.3	3.0
	304	200	298.8	7.5	2.5
Lot 2	43	200	42.1	2.0	4.8
	108	200	106.9	3.2	3.0
	304	200	304.1	8.0	2.6
Lot 3	43	200	42.2	2.8	6.6
	108	200	108.1	2.9	2.7
	304	200	308.6	7.3	2.4

*b. Linearity/assay reportable range:*

The sponsor evaluated the linearity of the meter by preparing a series of 10 glucose samples, following the dilution scheme in CLSI EP6-A, and producing target values of 11, 52, 89, 157, 234, 310, 386, 461, 531, and 607 mg/dL.

Each of the ten levels was analyzed five times using three lots of test strips on each of three meters. All samples were also tested on the YSI 2300 reference analyzer. Linear regression analysis of the data is summarized below:

Meter #	Slope	Intercept	Correlation coefficient (r <sup>2</sup> )
1	0.990	1.443	0.9995
2	0.979	2.422	0.9997
3	0.978	4.474	0.9992

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

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

Traceability:

The CERA-CHEK 1070 Blood Glucose Monitoring System is traceable to the YSI 2300 Glucose analyzer which is calibrated using the YSI 2747 Glucose Standard (a NIST traceable glucose standard).

Control Solution Value Assignment:

Two levels of aqueous control solutions (level 1 and 2) are available for use with the CERA-CHEK 1070 Blood Glucose Monitoring System. Ten replicates of each level of Control Solution were tested one each on four glucose meters. The 40 data points were compiled and the mean was used as the target concentration. Value assignment ranges were established at  $\pm 20\%$  around the target concentration. The target mean and ranges for each control solution are provided on the test strip vial label.

Stability:

Test strip shelf-life stability (closed vial) was assessed in an accelerated study with real time studies ongoing. The protocols and acceptance criteria were reviewed and found to be acceptable. The testing supported the claimed shelf life of 24 months when stored at 1-32°C and 10-85% relative humidity (RH).

Test strip in-use stability (open vial) was assessed in real time studies. The protocols and acceptance criteria were reviewed and found to be acceptable. The testing supported the open vial stability of 4 months when stored at 1-32°C and 10-85% RH.

Control shelf-life stability (closed vial) was assessed in real-time studies. The protocols and acceptance criteria were reviewed and found to be acceptable. The testing supported the claimed shelf life of 12 months when stored at 1-32° C.

Control in-use stability (open vial) was assessed in real-time studies. The protocols and acceptance criteria were reviewed and found to be acceptable. The testing supported the open vial stability of 4 months when stored at 1-32° C.

d. *Detection limit:*

The measuring range of the device is 20 - 600 mg/dL. This range was validated by the linearity study (M.1.b).

e. *Analytical specificity:*

The sponsor performed interference studies in accordance with CLSI EP7-A. Testing was performed in parallel (control samples vs. test samples) to minimize the effects of glucose metabolism. Whole blood was drawn into K<sub>3</sub>- EDTA anticoagulant tubes from healthy volunteers who were not on any medications. The glucose levels tested were 64, 151, and 257 mg/dL. The highest level was achieved by spiking. A low and high concentration of each potential interferent was then tested at each glucose level. The following substances were found not to interfere at the concentrations listed below:

Substance	No interference up to:
Acetaminophen	6 mg/dL
Ascorbic acid	4 mg/dL
Dopamine	5 mg/dL

Ibuprofen	40 mg/dL
Metformin	4 mg/dL
Methyldopa	5 mg/dL
Salicylic acid	50 mg/dL
Uric acid	10 mg/dL
Bilirubin	4 mg/dL
Triglyceride	1500 mg/dL
Cholesterol	500 mg/dL
Creatinine	10 mg/dL
Galactose	100 mg/dL
Gentisic acid	2 mg/dL
Glutathione	3 mg/dL
Hemoglobin	20 g/dL
L-Dopa	4 mg/dL
Maltose	100 mg/dL
Sodium	150 mmol/L
Tolbutamide	64 mg/dL
Tolazamide	5 mg/dL
Xylose	10 mg/dL
Mannitol	800 mg/dL
Sorbitol	100 mg/dL
Xylitol	100 mg/dL
Lactitol	100 mg/dL
Isomalt	100 mg/dL
Maltitol	100 mg/dL
Hydrogenated starch hydrolysates	100 mg/dL

The sponsor has the following limitations in their labeling:

- High concentrations of dopamine, methyldopa, and tolazamide may cause inaccurate test results.
- Do not use during or soon after xylose absorption testing. Xylose (> 10mg/dL) in the blood will cause interference.

*f. Assay cut-off:*

Not applicable.

2. Comparison studies:

*a. Method comparison with predicate device:*

Trained technicians performed fingertip measurements using the CERA-CHEK 1070 Blood Glucose Monitoring System on 200 study participants. Within five minutes, another

blood sample was collected from each participant and was tested on the YSI 2300 reference analyzer (results ranging from 52 to 386 mg/dL). In addition, trained technicians tested 18 contrived samples with glucose concentrations between 20 and 50 mg/dL or 400 and 600 mg/dL. The data analysis for the total 218 results is displayed below:

**System accuracy results vs. YSI for glucose concentrations <75 mg/dL**

within ±5mg/dL	within ±10mg/dL	within ±15mg/dL
77% (36/47)	89% (42/47)	100% (47/47)

**System accuracy results vs. YSI for glucose concentrations ≥ 75 mg/dL**

within ±5%	within ±10%	within ±15%	within ±20%
58% (100/171)	82% (140/171)	96% (164/171)	100% (171/171)

**Linear regression:**

N= 218	Slope	Intercept	Correlation coefficient
	(95% CI)		
Technician vs YSI	1.0365 (1.0223~1.0507)	-5.5769 (-8.2708~-2.8831)	0.9948

**Alternative Site Test (AST) by Professionals**

Alternate Site study was performed with a total of 100 volunteers' samples that had hematocrit between 35 and 50%. Samples of each alternative site were measured by both lay users and lab technicians. Another blood sample from each volunteer was collected and measured on YSI 2300 reference analyzer.

Results obtained by lab technicians are presented below:

**Difference distribution for glucose concentration <75mg/dL**

AST Site:	Palm	forearm	Upper arm	Thigh	Calf
within±5mg/dL.	80%(4/5)	60%(3/5)	100%(5/5)	80%(4/5)	80%(4/5)
within±10mg/dL	100%(5/5)	100%(5/5)	100%(5/5)	80%(4/5)	100%(5/5)
within±15mg/dL	100%(5/5)	100%(5/5)	100%(5/5)	100%(5/5)	100%(5/5)

**Difference distribution for glucose concentration ≥75mg/dL**

AST Site:	Palm	forearm	Upper arm	Thigh	Calf
within±5%	73%(70/95)	59%(56/95)	65%(62/95)	66%(63/95)	64%(61/95)
within±10%	78%(74/95)	71%(67/95)	77%(73/95)	77%(73/95)	71%(67/95)
within±15%	93%(88/95)	95%(90/95)	95%(90/95)	97%(92/95)	98%(93/95)
within±20%	100%(95/95)	100%(95/95)	100%(95/95)	100%(95/95)	100%(95/95)

**Linear regression and correlation coefficient**

	Slope	Intercept	Correlation coefficient (r <sup>2</sup> )
	(95% CI)		
Palm capillary vs YSI	1.023 (1.0054~1.0406)	2.1615 (-1.4008~5.7239)	0.9963
Forearm capillary vs YSI	1.0519	-0.0445	0.9967

	(1.0347~1.0692)	(-3.5308~3.4419)	
Upper arm capillary vs YSI	1.0396 (1.0202~1.0590)	0.0729 (-3.8584~4.0043)	0.9957
Thigh capillary vs YSI	1.0303 (1.0109~1.0496)	0.5266 (-3.3818~4.4350)	0.9957
Calf capillary vs YSI	1.0364 (1.0144~1.0583)	0.7075 (-3.7344~5.1494)	0.9945

b. *Matrix comparison:*

Not applicable. Only fresh capillary blood samples may be used with this device.

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**

200 participants collected and tested their own finger stick samples using the CERA-CHEK 1070 Blood Glucose Monitoring System. Within five minutes, another blood sample was collected from each participant and was tested on the YSI 2300 reference analyzer (results ranging from 54 to 427 mg/dL).

User accuracy results vs. YSI for glucose concentrations <75 mg/dL

within ±5mg/dL	within ±10mg/dL	within ±15mg/dL
55% (21/38)	87% (33/38)	100% (38/38)

User accuracy results vs. YSI for glucose concentrations ≥ 75 mg/dL

within ±5%	within ±10%	within ±15%	within ±20%
56% (91/162)	76% (123/162)	94% (152/162)	100% (162/162)

Linear regression:

N= 200	Slope	Intercept	Correlation coefficient
	(95% CI)		
Lay User vs YSI	1.0322 (1.0117~1.0527)	-3.0441 (-6.4963~0.1081)	0.9901

**Alternative Site Test by Lay Users**

Alternate Site study was performed with a total of 100 volunteers' samples that had hematocrit between 35 and 50%. Each lay user measured his/her own samples from each alternative site. Another blood sample from each lay user was also collected by a technician and measured on YSI 2300 reference analyzer. Results obtained by lay users are presented below:

Difference distribution for glucose concentration <75mg/dL

AST Site:	Palm	forearm	Upper arm	Thigh	Calf
within±5mg/dL.	80%(4/5)	80%(4/5)	80%(4/5)	80%(4/5)	80%(4/5)
within±10mg/dL	100%(5/5)	100%(5/5)	100%(5/5)	100%(5/5)	100%(5/5)
within±15mg/dL	100%(5/5)	100%(5/5)	100%(5/5)	100%(5/5)	100%(5/5)

Difference distribution for glucose concentration ≥75mg/dL

AST Site:	Palm	forearm	Upper arm	Thigh	Calf
within±5%	73%(70/95)	59%(56/95)	65%(62/95)	66%(63/95)	64%(61/95)
within±10%	78%(74/95)	71%(67/95)	77%(73/95)	77%(73/95)	71%(67/95)
within±15%	93%(88/95)	95%(90/95)	95%(90/95)	97%(92/95)	98%(93/95)
within±20%	100%(95/95)	100%(95/95)	100%(95/95)	100%(95/95)	100%(95/95)

Linear regression and correlation coefficient

	Slope	Intercept	Correlation coefficient (r <sup>2</sup> )
	(95% CI)		
Palm capillary vs YSI	1.0504 (1.0305~1.0704)	-1.5331 (-5.5767~2.5105)	0.9955
Forearm capillary vs YSI	1.0317 (1.0143~1.0491)	2.1956 (-1.3207~5.7120)	0.9965
Upper arm capillary vs YSI	1.0254 (1.0059~1.0448)	1.908 (-2.0296~5.8455)	0.9956
Thigh capillary vs YSI	1.0405 (1.0163~1.0648)	-0.9615 (-5.8634~3.9404)	0.9933
Calf capillary vs YSI	1.0352 (1.0170~1.0535)	1.7561 (-1.9340~5.4461)	0.9962

4. Clinical cut-off:

Not applicable.

5. Expected value/Reference range:

Expected blood glucose levels for people without diabetes (referenced from the American Diabetes Association, Diabetes Care, January 2013; vol. 36, Supplement 1, S67-S74)

Time	Range (mg/dL)
Before a meal	< 100
Two hours after meals	< 140

**N. Instrument Name:**

CERA-CHEK 1070 Blood Glucose Meter

**O. System Descriptions:**

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for additional measurements.

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

Yes  No

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

Yes  No

2. Software:

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

Yes  No

The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

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:

This device is intended to be used with fresh capillary whole blood which is applied directly to the test strip.

5. Calibration:

Each vial of strips contains a Code Key which is used to code the meter before use.

6. Quality Control:

Controls are not included in the starter kit, but the labeling explains how users can obtain two levels of controls. The labeling also provides recommendations on when to test control materials. An acceptable range for each control level is printed on the test strip vial label. If the control values fall outside these ranges, the user is instructed to repeat the control test. If the user continues to get out of range results, they are instructed not to use the system and to contact technical service.

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

1. Hematocrit study: The effect of different hematocrit levels was evaluated using venous whole blood samples with hematocrit levels across the claimed range and altered to glucose concentrations from 21 – 529 mg/dL. There were five measurements for each combination of glucose concentration and hematocrit level (8%, 19%, 28%, 40%, 48%, 61%, 72%). The results under each possible combination of glucose concentration and hematocrit level were compared to YSI results and demonstrated that the CERA-CHEK 1070 Blood Glucose Monitoring System produces accurate results over the claimed hematocrit range of 10 – 70%.
2. Altitude study: A study was conducted to evaluate the effect of altitude on the device. In this

evaluation, venous blood at glucose concentrations of approximately 100, 200, and 300 mg/dL were tested using a decompression chamber to simulate the effects of altitude. Three lots of test strips and three meters were used. Each blood sample was also tested by the YSI 2300 reference analyzer. The meter readings obtained were compared to the YSI method and the percent bias was determined at each level against the YSI results. The results demonstrated that the CERA-CHEK 1070 Blood Glucose Monitoring System produces accurate results at altitudes up to 13,200 feet.

3. Temperature and Humidity Studies: In this study, three test strip lots were tested on three meters at three glucose concentrations (approximately 45, 120, and 300 mg/dL) at twelve combinations of temperature and humidity. Each combination of environmental conditions / glucose concentration / meter was tested in replicates of three. The temperatures tested ranged from 10.0° C to 41.2° C. The relative humidity tested ranged from 10.3% - 86.6%. Glucose concentrations were verified by the YSI reference method. The bias relative to the reference method was acceptable to support the claim that temperatures from 10 – 40° C (50 – 104° F) and relative humidity from 10 – 85% do not significantly affect the glucose results.
4. Infection Control Studies: The Ceragem Medisys CERA-CHEK 1070 Blood Glucose Monitoring System is intended for single-patient use only. Disinfection efficacy studies were performed with the chosen disinfectant, CaviWipes (EPA Registration Number 46781-8) by an outside commercial testing facility, which demonstrated complete inactivation of hepatitis B virus (HBV). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials for the meter after 1825 cleanings and 1825 disinfection steps with CaviWipes. 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.
5. Electromagnetic Compatibility (EMC) and Electrical Safety Testing: Adequate electrical safety and EMC testing was conducted and acceptable certification provided.
6. Readability Assessment: The sponsor performed a reading level assessment of the labeling. The Flesch-Kincaid results were as follows:

User manual:	Grade level 7.2
Test strip insert:	Grade level 6.7
Control solution insert:	Grade level 7.6
7. Device Usability Study: A usability study was performed to assess the readability of the labeling by recruiting untrained lay users who were provided with the test kit and labeling. These lay users also completed a questionnaire regarding the clarity of the instructions and the ease of use of the device. The responses indicated that the instructions were understandable and adequate to successfully operate the device.
8. Data Management Software Usability Study: The sponsor also performed a human factors study with 30 lay users to evaluate the CERA-CHEK Diabetes Management Software (which included installing the transmission software and transferring the data from the meters to a PC), and concluded that the CERA-CHEK Diabetes Management Software demonstrated acceptable usability and data transmission accuracy.
9. Data Storage and Memory Roll-over Study: To assess the storage of the CERA-CHEK 1070 device and the memory data rollover function, 1020 data records were input into CERA-CHEK 1070 device. The integrity of the stored data was confirmed with an accuracy of

100% by comparing the 1000 data records on meter to the data transferred to computer via CERA-CHEK Diabetes Management Software. The study also demonstrated that the new data will replace the existing data order after the memory is full.

10. The sponsor provided the results of the device software testing including a hazard analysis, traceability analysis, validation and verification testing, and release level history which were reviewed and found to be adequate.
11. The Toll-free Customer Service number available 24 hours a day, 7 days a week is 1-800-903-9333.

**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.