

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

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

k122688

**B. Purpose for Submission:**

Modified Device to include a new glucose strip technology

**C. Measurand:**

Capillary whole blood glucose and  $\beta$ -hydroxybutyrate ( $\beta$ -ketone) in capillary whole blood

**D. Type of Test:**

Quantitative, amperometric, Glucose Dehydrogenase – FAD and quantitative amperometric  $\beta$ -ketone

**E. Applicant:**

Nova Biomedical Corporation

**F. Proprietary and Established Names:**

Nova Max Mini Blood Glucose and  $\beta$ -ketone Monitor System

**G. Regulatory Information:**

<b>Product Code</b>	<b>Classification</b>	<b>Regulation Section</b>	<b>Panel</b>
LFR-Glucose Dehydrogenase, glucose	Class II	21 CFR § 862.1345	75-Chemistry
NBW – system, test, blood glucose, over the counter	Class II	21 CFR § 862.1345	75-Chemistry
JIN – Nitroprusside, Ketones (urinary, non-quant.)	Class I, meets limitations of exemptions 862.9	21 CFR § 862.1435 Ketones (nonquantitative) test system	75-Chemistry

		21 CFR § 862.9(c)(9)	
JJY, Multi-Analyte Controls	Class I, reserved	21 CFR § 862.1660	75 – Chemistry

**H. Intended Use:**

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Nova Max Mini Blood Glucose and  $\beta$ -Ketone Monitor System is intended to be used for the quantitative measurement of glucose or  $\beta$ -hydroxybutyrate ( $\beta$ -ketone) in fresh capillary whole blood. It is intended for single-patient home use and should not be used for testing multiple patients. It is intended for self-testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. The Nova Max Mini Blood Glucose and  $\beta$ -Ketone Monitor System is specifically indicated for the quantitative measurement of glucose in fresh capillary whole blood obtained from the fingertip or alternative site testing on the forearm, or  $\beta$ -ketone in whole blood capillary samples obtained from the fingertip only. Glucose AST on the forearm can be used only during steady-state blood glucose conditions.

The Nova Max Mini is not intended for the diagnosis of or screening for diabetes, and it is not intended for use on neonates.

The Nova Max Mini Blood Glucose Test Strips are intended for use only with the Nova Max Mini Blood Glucose Monitor System to quantitatively measure capillary blood glucose from the finger and forearm.

The Nova Max Mini Ketone Test Strips are intended for use only on the Nova Max Mini Blood Glucose and  $\beta$ -Ketone Monitor System to quantitatively measure capillary  $\beta$ -hydroxybutyrate from the finger.

Nova Max Mini Glucose/Ketone Control Solutions are intended for use with the Max Mini Glucose or  $\beta$ -Ketone Test Strips as a quality control check to verify the accuracy of test results. There are two levels of controls, (Level 2 and Level 3).

3. Special conditions for use statement(s):

- For over-the-counter use.
- Not intended for the diagnosis or screening for diabetes mellitus.
- Not intended for use on neonates.
- For in vitro diagnostic use only.

- Not for use on patients who are dehydrated, hypotensive, in shock, or for individuals in hyperglycemic-hyperosmolar state, with or without ketosis.
- Critically ill patients should not be tested with a blood glucose meter.
- The meter and its accessories are for use by a single person.
- Alternative site testing should not be used for calibrating continuous glucose monitors, nor for insulin dosing calculations

4. Special instrument requirements:

Nova Max Mini Blood Glucose and  $\beta$ -Ketone Monitor

**I. Device Description:**

The Nova Max Mini Blood Glucose and  $\beta$ -Ketone Monitor System consists of: Nova Max Mini Blood Glucose and  $\beta$ -Ketone Monitor, 10 Nova Max Mini Glucose Test Strips, battery (3V cell), Nova Max Mini Blood Glucose and  $\beta$ -Ketone Monitor Owner's Guide, Nova Max Mini Blood Glucose and  $\beta$ -Ketone Monitor Quick Reference Guide, Nova Max Mini Log Book, Lancing Device with Alternate Site Testing Cap, 10 Lancets, 2 Nova Max Mini Ketone Test Strips, Nova Max Mini Glucose/Ketone Control Solution (Level 2), Warranty Card, and Day Case. The following are items sold separately: Nova Max Mini Glucose/Ketone Control Solutions (Level 2 and Level 3), Nova Max Mini Test Strips (vials of 50 strips), and Nova Lancets.

The glucose test strips utilized in the Nova Max Mini Blood Glucose and  $\beta$ -Ketone Monitor are the same as the Nova Max One glucose test strips, previously cleared in k112638 and the ketone test strips are the same as the Nova Max Plus Ketone test strips, previously cleared in k091547.

1. Predicate device name(s):

Nova Max Plus Blood Glucose and  $\beta$ -Ketone Monitor System

Nova Max One Blood Glucose Monitor System

Nova Max Plus Glucose and  $\beta$ -Ketone Control Solutions

2. Predicate K number(s):

k091547

k112638

k101633

3. Comparison with predicate:

Characteristic	<b>Predicate</b> - Nova Max One Blood Glucose Monitor System - K112638	<b>Predicate</b> – Nova Max Plus Blood Glucose and $\beta$ -Ketone Monitor System – K091547	<b>Proposed</b> - Nova Max Mini Blood Glucose and $\beta$ -Ketone Monitor System
Test Measured	Glucose	Glucose or $\beta$ -Ketone	Glucose or $\beta$ -Ketone
Operating Principle	Coulometric Electro-chemical Sensor	Coulometric Electro-chemical Sensor	Coulometric Electro-chemical Sensor
Intended Use	<p>The Nova Max One Blood Glucose Monitor is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. It is intended for single-patient home use and should not be used for testing multiple patients. It is intended for self testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. The Nova Max One Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in fresh whole blood capillary samples obtained from the fingertip or alternative site testing (AST) on the forearm. AST on the forearm can be used only during steady-state blood glucose conditions. It is not intended for the diagnosis of or screening for diabetes, and it is not intended for use on newborns.</p>	<p>The Nova Max Plus Glucose and <math>\beta</math>-Ketone Monitoring System is intended to be used for the quantitative measurement of glucose or <math>\beta</math>-hydroxybutyrate (<math>\beta</math>-Ketone) in fresh capillary whole blood. It is intended for use by people with diabetes mellitus in the home and by healthcare professionals in clinical settings as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. The Nova Max Plus Monitor is specifically indicated for the quantitative measurement of glucose in fresh capillary whole blood samples obtained from the fingertip, forearm, and palm or <math>\beta</math>-ketone in fresh capillary whole blood samples obtained from the fingertip only.</p>	<p>The Nova Max Mini Blood Glucose and <math>\beta</math>-Ketone Monitor System is intended to be used for the quantitative measurement of glucose or <math>\beta</math>- hydroxybutyrate (<math>\beta</math>-ketone) in fresh capillary whole blood. It is intended for single-patient home use and should not be used for testing multiple patients. It is intended for self-testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. The Nova Max Mini Blood Glucose and <math>\beta</math>-Ketone Monitor System is specifically indicated for the quantitative measurement of glucose in fresh capillary whole blood obtained from the fingertip or alternative site testing on the forearm, or <math>\beta</math>-ketone in whole blood capillary samples obtained from the fingertip only. Glucose AST on the forearm can be used only during steady-state blood glucose conditions.</p> <p>The Nova Max Mini is not intended for the diagnosis of or screening for diabetes, and it is not intended for use on neonates.</p> <p>The Nova Max Mini Blood Glucose Test Strips are intended for use only with the Nova Max Mini Blood Glucose Monitor System to quantitatively measure capillary blood glucose from the finger and forearm.</p> <p>The Nova Max Mini Ketone Test Strips are intended for use only on the Nova Max Mini Blood Glucose and <math>\beta</math>-Ketone Monitor System to quantitatively measure capillary <math>\beta</math>- hydroxybutyrate from the finger.</p>

GLU Measuring Range	20-600 mg/dL	20-600 mg/dL	20-600 mg/dL
KET Measuring Range	N/A	0.1 – 8.0 mmol/L	0.1 – 8.0 mmol/L
Hematocrit Range	25% to 60%	25% to 60%	25% to 60%
Sample type	Capillary blood from the fingertip, forearm	Capillary blood from the fingertip, forearm and palm (Ketone fingertip only)	Capillary blood from the fingertip, forearm (Ketone fingertip only)
GLU Sample size	0.4 µL	0.3 µL	0.4 µL
Glucose Units	mg/dL	mg/dL	mg/dL
Ketone Units	N/A	mmol/L	mmol/L
Sample application	Test strip capillary draw	Test strip capillary draw	Test strip capillary draw
Handheld meter	Yes	Yes	Yes
Data storage	Up to 400 blood glucose and control solution tests	Up to 400 blood glucose and control solution tests	Up to 400 blood glucose and control solution tests
GLU Analysis Time	4 seconds	5 seconds	4 seconds
Insulin Tracking	No.	No	No.
KET Analysis Time	N/A	10 seconds	10 seconds
Power source	3 volt coin cell battery	3 volt coin cell battery	3 volt coin cell battery
GLU Test Strips Active reagent:	Glucose Dehydrogenase – FAD	Glucose Oxidase	Glucose Dehydrogenase – FAD
KET Test Strips Active reagent	N/A	β-hydroxybutyrate dehydrogenase	β-hydroxybutyrate dehydrogenase
Test Strip Calibration Coding	No User Input of Calibration code required	No User Input of Calibration code required	No User Input of Calibration code required

Characteristic	<b>Predicate</b> - Nova Max Plus Blood Glucose and $\beta$ -Ketone Monitor (Predicate Device k101633)	<b>Predicate</b> – Nova Max Plus Blood Glucose and $\beta$ -Ketone Monitor System –
Intended Use	Intended as a quality control check to verify accuracy of blood glucose and $\beta$ -Ketone test results.	Same
Analyte(s)	Glucose and $\beta$ -Ketone	Same
Levels of Controls	2 Levels: Mid and High	2 Levels: Levels 2 and 3

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

1. EN55011: Limits and Methods of Measurement of Radio Disturbance Characteristics of Indl., Scient., and Med. RF Equipment, 1, B.
2. IEC 60601: Medical electrical equipment – Part 1-2: General requirements for safety- Coll. Standard: Electromagnetic compatibility
3. IEC 61010-1: Safety requirements for electrical equipment for measurement, control, and laboratory use-Part 1: Gen. Requirements
4. ISO 15197:2003 In vitro diagnostic test systems—Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
5. EP05-A2 Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition
6. EP06-A Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline—Second Edition
7. EP07-A2 Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition

**L. Test Principle:**

Glucose measurement is based on electrochemical biosensor technology using the enzyme glucose dehydrogenase - FAD. The glucose in the sample is oxidized to produce glucuronic acid. The electrical current resulting from this enzymatic reaction is measured and correlated to glucose concentration by the meter. The magnitude of the current is proportional to the concentration of glucose in the sample. The test strip is calibrated to display the equivalent of plasma glucose values to allow comparison of results with laboratory methods. Using the same technology,  $\beta$ -hydroxybutyrate ( $\beta$ - ketone) is converted by  $\beta$ -hydroxybutyrate dehydrogenase and the magnitude of electrical current resulting from this enzymatic reaction is proportional to the amount of  $\beta$ - hydroxybutyrate present in

the sample.

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

The glucose test strips (Glucose dehydrogenase-FAD enzyme) utilized in the Nova Max Mini Blood Glucose and  $\beta$ -Ketone Monitor are the same as the Nova Max One glucose test strips, previously cleared in k112638 and the ketone test strips are the same as the Nova Max Plus Ketone test strips, previously cleared in k091547.

The Nova Max Mini Blood Glucose and  $\beta$ -Ketone Monitor, while smaller than both the Nova Max Plus (k091547) and the Nova Max One (k112638) Monitors, has the same fundamental scientific technology and user interface. The only changes made to the components of the system as compared to the cleared systems (k091547 and k112638) are the smaller housing and display.

1. Analytical performance:

a. *Precision/Reproducibility:*

Whole Blood Glucose:

Within-run precision was measured using heparinized venous whole blood samples at six different glucose concentrations. Each sample was tested on 3 lots of test strips on six meters. Five replicates were tested per meter, test strip lot, and glucose concentration, (N=90 per glucose concentration tested). Results are summarized below:

Glucose Level (mg/dL)	Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
30 – 80 mg/dL	1	60.3	2.2	3.7
	2	59.9	2.8	4.7
	3	60.0	1.9	3.2
100-200 mg/dL	1	146.0	3.5	2.4
	2	146.0	4.5	3.1
	3	145.1	3.3	2.2
200-300 mg/dL	1	278.3	8.9	3.2
	2	281.1	9.0	3.2
	3	278.0	8.0	2.9
300-400 mg/dL	1	376.9	9.7	2.6
	2	375.5	9.2	2.5
	3	375.6	11.0	2.9
400-500 mg/dL	1	476.6	13.6	2.9
	2	477.5	13.5	2.8

	3	474.5	15.6	3.3
500-600 mg/dL	1	554.4	15.1	2.7
	2	562.0	16.0	2.9
	3	559.8	14.9	2.7

Combined results (3 Test Strip Lots)

Blood Glucose Level (mg/dL)	Mean (mg/dL)	SD	CV%
30 – 80	60.6	2.34	3.9
100 – 200	145.68	3.79	2.6
200 – 300	279.13	8.67	3.1
300 – 400	375.99	9.92	2.6
400 – 500	476.17	14.17	2.9
500 – 600	558.7	15.52	2.8

Whole Blood Ketone:

Within-run precision was measured using heparinized venous whole blood samples at five different  $\beta$ - ketone concentrations. Each sample was tested on 3 lots of test strips on five meters. Four replicates were tested per meter (N=20 per meter), test strip lot, and  $\beta$  -ketone concentration. Results are summarized below:

$\beta$ -Ketone Level (mM)	Strip Lot	Mean (mM)	SD (mM)
0.1-0.6 mM	1	0.5	0.06
	2	0.5	0.06
	3	0.48	0.06
1.0 – 2.0 mM	1	1.59	0.07
	2	1.61	0.07
	3	1.59	0.06
3.0 – 4.0 mM	1	3.33	0.14
	2	3.40	0.15
	3	3.37	0.14
5.0 – 6.0 mM	1	5.51	0.22
	2	5.59	0.23
	3	5.49	0.23
6.5 – 8.0 mM	1	7.23	0.25
	2	7.32	0.25
	3	7.29	0.23

**Between Day Precision: Glucose**

A between day precision study was performed using four levels of glucose control solutions (Level 1, Level 2, Level 3, Level 4) utilizing three lots of glucose test strips. One measurement was obtained in the morning and one measurement was obtained in the afternoon for 10 days on two meters (one strip per meter).

Control Levels	Strip Lot 1 n=40			Strip Lot 2 n=40			Strip Lot 3 n=40		
	Mean	CV%	S.D.	Mean	CV%	S.D.	Mean	CV%	S.D.
Level 1 (40 – 60 mg/dL)	50.1	3.7	1.9	51.1	4.2	2.1	50.3	3.7	1.8
Level 2 (98 – 130 mg/dL)	117.7	3.2	3.7	115.8	2.8	3.2	116.8	3.3	3.8
Level 3 (280 – 380 mg/dL)	328.6	2.5	8.1	326.0	2.2	7.1	326.5	2.1	6.7
Level 4 (440 – 570 mg/dL)	510.4	2.3	11.7	515.5	2.4	12.4	518.7	2.3	12.0

**Between Day Precision: Whole Blood Ketone:**

A between day precision study was performed using four levels of ketone solution (Level 1, Level 2, Level 3, Level 4) utilizing three lots of ketone strips. One measurement was obtained in the morning and one measurement was obtained in the afternoon for 10 days on two meters (one strip per meter).

Control Levels	Strip Lot 1 n=40		Strip Lot 2 n=40		Strip Lot 3 n=40	
	Mean	S.D.	Mean	S.D.	Mean	S.D.
Level 1 (0.1 – 0.3 mM)	0.13	0.05	0.14	0.05	0.14	0.05
Level 2 (0.4 – 0.8 mM)	0.59	0.06	0.59	0.06	0.59	0.06
Level 3 (1.5 – 2.5 mM)	1.98	0.07	2.00	0.08	1.98	0.08
Level 4 (2.8 – 4.2 mM)	3.44	0.16	3.48	0.16	3.37	0.16

*b. Linearity/assay reportable range:*

The glucose test strips (Glucose dehydrogenase-FAD enzyme) utilized in the Nova Max Mini Blood Glucose and  $\beta$ -Ketone Monitor are the same as the

Nova Max One glucose test strips, previously cleared in k112638 and the ketone test strips are the same as the Nova Max Plus Ketone test strips, previously cleared in k091547. Linearity data was previously reviewed in k112638 (glucose) and k091547 ( $\beta$ -ketone).

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

Traceability: Nova Max Mini Blood Glucose and  $\beta$ -ketone Monitor System is traceable to NIST SRM 917b reference material (glucose) and gravimetrically prepared in-house  $\beta$ -hydroxybutyrate standard stock solution obtained from a commercial source ( $\beta$ -ketone).

Nova Max Mini Glucose/Ketone Control Solutions previously cleared: See k101633 for traceability, stability, and expected value information.

Test strips previously cleared: See k091547 for stability information regarding  $\beta$ -ketone test strips and k112638 regarding glucose test strips (glucose-dehydrogenase-FAD enzyme)

*d. Detection limit:*

See linearity study above.

*e. Analytical specificity:*

The glucose test strips (Glucose dehydrogenase-FAD enzyme) utilized in the Nova Max Mini Blood Glucose and  $\beta$ -Ketone Monitor are the same as the Nova Max One glucose test strips, previously cleared in k112638 and the ketone test strips are the same as the Nova Max Plus Ketone test strips, previously cleared in k091547. Analytical specificity data previously reviewed in k112638 (glucose) and k091547 ( $\beta$ -ketone).

*f. Assay cut-off:*

Not applicable.

2. Comparison studies:

*a. Method comparison with predicate device:*

**System Accuracy: Ketone**

The sponsor conducted a method comparison study comparing the Nova Max Mini monitor vs (Stanbio system) enzymatic spectroscopy reference method. A total of 100 heparinized venous whole blood samples were prepared to span the claimed measuring range: 0.1 mM – 8 mM. Three lots of test strips were

used for this study for a total of N=300 per method.

Results of linear regression analysis are as follows:

Nova Mini ketone vs reference method:

$$y=1.0167x - 0.0577$$

$$R^2= 0.9931$$

**System Accuracy: Glucose**

The sponsor conducted a method comparison study comparing the Nova Max Mini meter vs YSI reference method following guidance from ISO 15197:2003. A total of 100 heparinized venous whole blood samples were prepared to span the claimed measuring range: 20 – 600 mg/dL. There were 7% glucose stock solution spiked samples and 7% glycolyzed samples. Three lots of test strips were used for this study for a total of N=100 samples.

Results of linear regression analysis are as follows:

Nova Mini glucose vs reference method:

$$y=1.0142x - 0.8658$$

$$R^2= 0.9953$$

System accuracy results for glucose concentration <75 mg/dL

Strip Lot	Within±5 mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
1	16/17 (94.1%)	17/17 (100%)	17/17 (100%)
2	16/17 (94.1%)	17/17 (100%)	17/17 (100%)
3	13/17 (76.5%)	17/17 (100%)	17/17 (100%)
Combined	45/51 (88.2%)	51/51 (100%)	51/51 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Strip Lot	Within±5%	Within± 10%	Within± 15%	Within±20 %
1	70/83 (84.3%)	81/83 (97.6%)	83/83 (100%)	83/83 (100%)
2	67/83 (80.7%)	81/83 (97.6%)	83/83 (100%)	83/83 (100%)
3	67/83 (80.7%)	83/83 (100%)	83/83 (100%)	83/83 (100%)

Combined	204/249 (81.9%)	245/249 (98.4%)	249/249 (100%)	249/249 (100%)
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*b. Matrix comparison:*

None. Only capillary whole blood samples are acceptable matrix.

3. Clinical studies:

*a. Clinical Sensitivity:*

Not applicable.

*b. Clinical specificity:*

Not applicable.

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

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Normal  $\beta$ -Ketone Values: The normal adult blood  $\beta$ -Ketone range for a person without diabetes is less than 0.6 mmol/L<sup>1</sup>

Normal Glucose Values: The normal fasting adult blood glucose range for a person without diabetes is <100 mg/dL. 1 One to two hours after meals, normal blood glucose levels should be less than 140 mg/dL<sup>2</sup>

1. Rewers, Arleta, MD, PhD, 2010, *Current Controversies in Treatment and Prevetion of Diabetic Ketoacidosis*, Advances in Pediatrics 57 (2010) 217-267
2. American Diabetes Association, Clinical Practice Recommendations (2013) Diabetes Care, Vol 36, Supplement 1, p S1-S100

**N. Instrument Name:**

Nova Max Mini Blood Glucose and  $\beta$ -Ketone Monitor

**O. System Descriptions:**

1. Modes of Operation:

Each test strip is single use and requires a sample volume of 0.4  $\mu$ L for glucose measurements and 0.8 $\mu$ L for ketone measurements.

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

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

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

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

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 glucose test is intended to be used with capillary whole blood from the finger, and forearm only. The  $\beta$ -ketone test is intended to be used with capillary whole blood from fingerstick only. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

There is no calibration required for the Nova Max Mini Blood Glucose and B-Ketone monitor by the user. The meter is plasma-calibrated for glucose..

6. Quality Control:

Glucose and  $\beta$ -ketone control solutions at two different concentrations can be run with this device. The meter has an algorithm to recognize the control solutions to prevent control results from being stored in the internal memory as patient result.

Recommendations on when to test the control materials are provided in the labeling. 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 glucose and  $\beta$ -ketone test strip vial labels. 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. Usability Study:

A usability study was conducted at one site with forty enrolled participants. The participants were divided into two focus groups. Each participant was identified as either having type 1 or type 2 diabetes performing regular self-monitoring of blood glucose levels at home ( $\geq 1$  month regular self-monitoring). Each enrolled participant was at least 18 years of age and willing to complete all study procedures. Each participant was asked to read the following labeling material: Owner’s guide, quick reference guide, glucose and  $\beta$ -ketone control solution (levels 1,2,3) package inserts, and glucose and  $\beta$ -ketone test strip package inserts. Subsequently, each participant was given a questionnaire evaluating each reading material provided for the study. The ease of use of the Nova Max Mini meter was evaluated by asking each participant to perform testing functions and by using the meter with glucose and  $\beta$ -ketone control solutions. Additionally, each participant’s ability to distinguish between glucose and  $\beta$ -ketone measurements was evaluated using control solution materials.

Overall, the study participants found the labeling materials easy to comprehend and the Nova Max Mini Blood Glucose and  $\beta$ -ketone monitoring system easy to use. All participants were able to differentiate between a glucose and a  $\beta$ -ketone measurement.

2. Altitude Study :

The effect of varying altitudes previously reviewed in the Nova Max Plus Blood Glucose and  $\beta$ -ketone submission (k091547).

3. Hematocrit Study:

The effect of hematocrit previously reviewed in the Nova Max Plus Blood Glucose and  $\beta$ -ketone submission (k091547)

4. Temperature and Relative Humidity Study:

The effect of temperature and relative humidity previously evaluated in the Nova Max Plus Blood Glucose and  $\beta$ -ketone submission (k091547).

5. EMC Electromagnetic Compatibility and Electrical Safety verification testing of

the Nova Max Mini Blood Glucose and  $\beta$  ketone Monitoring System was performed following the requirements of EN60601-1-1-2:2007, EN61000-4-2, EN61000-4-3, EN61000-4-8, and EN55011 with a “Certification of Test” issued by The Compliance Management Group on June 28, 2012.

6. Sample volume study:

The effect of varying sample volumes previously evaluated in the Nova Max Plus Blood glucose and  $\beta$ -ketone submission (k091547).

7. Infection control:

The device system is intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meter and lancing device by an outside commercial testing demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Clorox Germicidal Wipes, EPA Reg. No. 67619-12. Robustness studies were also performed by the sponsor demonstrating that there was not change in performance or external materials of the meter and lancing device after 1,095 times of cleaning and disinfection cycles for the meter and 300 times for the lancing device, using Clorox Germicidal Wipes, EPA Reg. No. 67619-12 disinfectant wipes, to simulate 3 years of use by lay users. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

8. Readability: A Flesch-Kincaid analysis was conducted and the resulting grade level at which the device labeling is written is as follows:

Labeling	Flesch-Kincaid Grade Level Score
User’s Manual	6.0
Glucose Test Strip Insert	7.0
Ketone Test Strip Insert	6.8
Glucose and $\beta$ -ketone Control Solution Inserts	5.1

**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.