

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

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

k091547

**B. Purpose for Submission:**

Addition of ketone measurement component to already existing device

**C. Measurand:**

Glucose and B-hydroxybutyrate (B-ketone) in fresh capillary whole blood

**D. Type of Test:**

Quantitative amperometric, glucose oxidase and quantitative amperometric  $\beta$ -ketone

**E. Applicant:**

Nova Biomedical Corporation

**F. Proprietary and Established Names:**

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

**G. Regulatory Information:**

Product Code	Classification	Regulation Section	Panel
NBW - System, Test, Blood Glucose, Over the Counter CGA - Glucose Oxidase, Glucose	Class II	21 CFR 862.1345 – Glucose Test System.	75 Clinical Chemistry(CH)
Product Code	Classification	Regulation Section	Panel
JIN- Nitroprusside, Ketones (urinary, non-quant.)	Class I - meets limitations of exemptions 862.9	21 CFR 862.1435 Ketones (nonquantitative) test system 21 CFR 862.9(c)(9)	75 Clinical Chemistry(CH)
Product Code	Classification	Regulation Section	Panel
JJX- single (specified) analyte controls (assayed and unassayed)	Class I reserved	21 CFR 862.1660 Quality control material (assayed and unassayed)	75 Clinical Chemistry(CH)

**H. Intended Use:**

1. Intended use(s):  
See indications for use below.
2. Indication(s) for use:

The Nova Max Plus Blood Glucose and  $\beta$ -Ketone Monitoring System Monitor is intended to be used for the quantitative measurement of glucose 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 Blood Glucose and  $\beta$ -Ketone Monitor is specifically indicated for the quantitative measurement of glucose in fresh capillary whole blood samples obtained from the fingertip, forearm and palm and  $\beta$ -hydroxybutyrate ( $\beta$ -ketone) in capillary whole blood from the finger only.

Nova Max Glucose Test Strips are intended for use only with the Nova Max Blood Glucose Monitor and the Nova Max Plus Blood Glucose and  $\beta$ -Ketone Monitor. The Glucose Monitor is calibrated to provide plasma equivalent glucose results to laboratory methods. Nova Max Blood Glucose Test Strips are for testing outside the body (in vitro diagnostic use only).

The Nova Max Plus Ketone Test Strips are intended for use only on the Nova Max Plus Blood Glucose and  $\beta$ -Ketone Monitor.

Nova Max Glucose Control Solutions are intended for use with the Nova Max Blood Glucose Monitor, the Nova Max Plus Blood Glucose and  $\beta$ -Ketone Monitor and Nova Max Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results. There are three levels of controls, (Normal, Low, High).

Nova Max Plus Ketone Control Solutions are intended for use with Nova Max Plus Blood Glucose and  $\beta$ -Ketone Monitor and Nova Max  $\beta$ -Ketone Test Strips as a quality control check to verify the accuracy of blood ketone test results. There are three levels of controls, (Levels 1,2 and 3).

3. Special conditions for use statement(s):

For in vitro diagnostic use only.

For Over-the-Counter use.

Not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The device should not be used for patients who are dehydrated, in shock, critically ill or in a hyperosmolar state.

The alternative site (forearm and the palm) testing in the Nova Max Plus Blood Glucose and  $\beta$ -Ketone Monitoring System is for glucose measurement only and can be used only during steady-state blood glucose conditions. Forearm or palm should not be used for  $\beta$ -ketone testing.

Alternative site testing (AST) should ONLY be used in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since the last meal)

- Two hours or more after taking insulin
- Two hours or more after exercise

4. Special instrument requirements:

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

**I. Device Description:**

The Nova Max Plus Blood Glucose and  $\beta$ -Ketone Monitoring System consists of: Nova Max Plus Blood Glucose and  $\beta$ -Ketone Monitor, Nova Max Glucose Test Strips, Nova Max Glucose Control Solutions (Normal, Low and High), Nova Max Plus  $\beta$ -Ketone Test Strips, and Nova Max Plus  $\beta$ -Ketone Control Solutions (Levels 1,2 and 3). The sponsor recommends that only corresponding Nova test strips and control solutions specified in the manual be used with the device. The performance of the test strips is verified by the control solutions.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Nova Max Blood Glucose Monitor  
Precision Xtra Advanced Diabetes Management System

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

k070255; k040814

3. Comparison with predicate:

**Similarities and Differences- Glucose**

<b>Characteristic</b>	<b>Proposed Device Nova Max Plus Blood Glucose and <math>\beta</math>-Ketone Monitor System</b>	<b>Predicate Device Nova Max Blood Glucose Monitor k070255</b>
<b>Intended Use</b>	The Nova Max Plus Blood Glucose and $\beta$ -Ketone Monitoring System is intended to be used for the quantitative measurement of glucose in 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 Blood Glucose and $\beta$ -Ketone Monitor is specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip, palm and forearm. The Nova Max Plus is also intended for the quantitative measurement of $\beta$ -hydroxybutyrate ( $\beta$ -ketone) in fresh capillary whole blood	The Nova Max Blood Glucose Monitor is intended to be used for the quantitative measurement of glucose in whole blood. It is intended for use by people with diabetes mellitus in the home 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 Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip, palm and forearm.

<b>Characteristic</b>	<b>Proposed Device Nova Max Plus Blood Glucose and β-Ketone Monitor System</b>	<b>Predicate Device Nova Max Blood Glucose Monitor k070255</b>
<b>Test Measured</b>	Same as Predicate	Glucose
<b>Measuring Range</b>	Same as Predicate	20-600 mg/dL
<b>Assay Method</b>	Same as Predicate	Glucose oxidase biosensor
<b>Glucose Units</b>	Same as Predicate	mg/dL (USA)
<b>Sample type</b>	Same as Predicate	Capillary blood: fingertip, forearm, palm
<b>Sample size</b>	Same as Predicate	0.3 uL
<b>Sample application</b>	Same as Predicate	Test strip capillary draw
<b>Hematocrit Range</b>	Same as Predicate	25%-60%
<b>Operating Temperature Range</b>	Same as Predicate	14C – 40 C
<b>Operating Relative Humidity</b>	Same as Predicate	10 %- 90% RH
<b>Diabetes Software for data management</b>	Same as Predicate	Utilizes Nova Diabetes Software, k023219, for data management
<b>Handheld meter?</b>	Same as Predicate	Yes
<b>Data storage</b>	Same as Predicate	Up to 400 memory events
<b>Analysis Time</b>	Same as Predicate	5 sec
<b>Weight</b>	Same as Predicate.	2.65 oz.
<b>Insulin Tracking feature</b>	Same as Predicate	No
<b>Power source</b>	Same as Predicate	3 volt coin cell battery
<b>Accessories to the Monitor:</b>		
<b>Controls:</b>	Same as Predicate	Liquid, 3 levels
<b>Glucose Test Strips: Active reagent: Glucose</b>	Same as Predicate	Glucose Oxidase
<b>Test Strip Calibration Coding</b>	Same as Predicate.	No User Input required for Nova Max;

#### Similarities and Differences- Ketone

<b>Characteristic</b>	<b>Proposed Device Nova Max Plus Blood Glucose and β-Ketone Monitor System</b>	<b>Predicate Device Abbott Precision Xtra Advanced Diabetes Management System k040814</b>
<b>Test Measured</b>	Same as Predicate	Blood β-Ketone
<b>Measuring Range</b>	0.1 to 8.0 mmol/L	Up to 8.0 mmol/L

<b>Characteristic</b>	<b>Proposed Device Nova Max Plus Blood Glucose and β-Ketone Monitor System</b>	<b>Predicate Device Abbott Precision Xtra Advanced Diabetes Management System k040814</b>
<b>Operating Principle</b>	Same as Predicate	β-hydroxybutyrate dehydrogenase biosensor
<b>Intended Use</b>	<p>The Nova Max Plus Blood Glucose and β-Ketone Monitoring System is intended to be used for the quantitative measurement of glucose in 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 Blood Glucose and β-Ketone Monitor is specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip, palm and forearm.</p> <p>The Nova Max Plus is also intended for the quantitative measurement of β-hydroxybutyrate (β-ketone) in fresh capillary whole blood.</p>	<p>The Precision Xtra Advanced Diabetes Management System is intended for in vitro diagnostic use (i.e., external use only) for the quantitative measurement of glucose in fresh capillary whole blood. The Precision Xtra is also intended for the quantitative measurement of β-hydroxybutyrate (β-ketone) in fresh capillary whole blood The Precision Xtra system is indicated for home (lay user) or professional use in the management of patients with diabetes.</p> <p>The Precision Xtra System may also be used for the quantitative measurement of glucose in venous, arterial or neonatal whole blood and ketone in venous blood, provided the sample is used within 30 minutes after collection.</p>
<b>Sample type</b>	Same as Predicate	Whole Blood Capillary
<b>Sample size</b>	0.8 uL	1.5 uL
<b>Ketone Units</b>	0.1 – 8.0 mmol/L	Up to 8.0mmol/L
<b>Sample application</b>	Same as Predicate	Test strip capillary draw
<b>Hematocrit Range</b>	25%-60%	30%-60%
<b>Operating Temperature Range</b>	59°F – 86°F	64°F – 86°F
<b>Operating Relative Humidity</b>	10%- 90% RH	10% - 90% RH
<b>Handheld meter?</b>	Yes	Yes
<b>Data storage</b>	Up to 400 memory events	Up to 450 memory events
<b>Analysis Time</b>	Same as Predicate	10 sec
<b>Weight</b>	2.65 oz	1.48 oz.
<b>Power source</b>	3 volt coin cell battery CL 2450	3 volt coin cell battery CR 2032
<b>Accessories to the Monitor:</b>		
<b>Controls:</b>	Nova Max Max Plus Ketone Control Solutions	Precision/Optium/Medisense Control Solutions
<b>Test Strips : Active reagent:</b>	Same as Predicate	B-hydroxybutyrate dehydrogenase
<b>Test Strip Calibration</b>	No User Input required for Nova Max.	ROM Calibrator

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

- CLSI EP-5A2: Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline

- CLSI EP-6A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline
- CLSI EP7-A: Interference testing in clinical chemistry; Approved Guideline.
- IEC 61010-1 2001 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General
- IEC 61010-2-101: 2002 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Particular requirements for In Vitro Diagnostic (IVD) Medical Equipment

**L. Test Principle:**

Glucose measurement is based on electrochemical biosensor technology using the enzyme glucose oxidase. The glucose in the sample is oxidized to produce gluconic 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):**

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision testing for  $\beta$ -ketone was performed on three levels of control solutions and five venous blood samples spiked with various concentrations of  $\beta$ -ketone. Sixty samples were assayed for the venous blood samples and thirty-six samples were assayed for the control solutions. Three lots of test strips were tested using the venous blood samples and the control solutions. Samples were assayed in replicates of four on each of five monitors. The sponsor conducted day-to-day precision studies using three levels of three levels of control solutions. Results are summarized in the tables below.

Within Run Precision Testing – Blood Samples

Ketone Concentration levels	Strip Lot 1 N=20/concentration level		Strip Lot 2 N=20/concentration level		Strip Lot 3 N=20/concentration level	
	Mean (mM)	CV (%) /SD	Mean (mM)	CV(%) /SD	Mean (mM)	CV(%) /SD
0-0.6mM	0.11	-/0.055	0.14	-/0.059	0.11	-/0.055
1.0-2.0mM	1.43	3.7/0.052	1.46	3.4/0.050	1.44	4.7/0.068
3.0-4.0mM	3.19	4.4/0.139	3.10	4.7/0.147	3.05	3.9/0.119
5.0-6.0mM	5.97	4.0/0.237	5.84	3.8/0.223	5.96	3.7/0.223
6.5-8.0mM	7.75	3.6/0.282	7.71	3.0/0.228	7.80	3.0/0.234

Within Run Precision Testing- Control Solutions

Control solution levels	Strip Lot 1 N=20/concentration level		Strip Lot 2 N=20/concentration level		Strip Lot 3 N=20/concentration level	
	Mean (mM)	CV (%)	Mean (mM)	CV (%)	Mean (mM)	CV (%)
Level 1	1.30	3.0	1.33	4.2	1.25	4.1
Level 2	2.84	5.4	2.85	5.4	2.82	5.5
Level 3	5.23	3.5	5.21	3.6	5.16	3.3

Day-to-Day Precision

Control Levels	Lot 1 n=80		Lot 2 n=80		Lot 3 n=80	
	mean	CV%	mean	CV%	Mean	CV%
Level 1 1.0-1.6mM	1.26	5.14	1.23	4.77	1.23	4.40
Level 2 2.5-3.5mM	2.85	5.30	2.84	5.51	2.85	4.36
Level 3 4.5-6.0mM	5.23	3.81	5.15	4.08	5.09	3.98

The precision studies for blood glucose measurement were addressed in the sponsor's predicate device (Nova Max Blood Glucose Monitor –k070255) that uses the same glucose test strips. However, the sponsor conducted additional precision studies to demonstrate the precision for glucose measurements are maintained in the new device.

*b. Linearity/assay reportable range:*

A linearity study was conducted using venous blood samples with  $\beta$ -ketone concentrations of 0.07, 0.28, 1.5, 2.42, 3.48, 4.61, 5.24, 7.13, 8.13 mM. Samples were tested 10 times on 5 meters using 3 lots. The samples were prepared by spiking blood with ketone. Samples were also assayed using a reference reagent. The summary of linear regression analyses of data generated based on the lot number is given in the table below. Based on the linearity studies, the sponsor claimed the ketone measuring range of the device is 0.1 – 8.0 mmol/L.

Strip Lot Numbers N=10	Slope	Intercept	R <sup>2</sup>
061608	0.9546	0.0645	0.9928
061708	0.9855	-0.0137	0.9934
061808	0.9741	0.0597	0.9893

The linearity studies for blood glucose measurement were addressed in the sponsor's predicate device (Nova Max Blood Glucose Monitor –k070255) that uses the same glucose test strips.

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

To demonstrate the shelf-life stability of the Nova Max Plus Ketone Test Strips, the sponsor conducted real time testing at 25<sup>0</sup>C and accelerated testing at 30<sup>0</sup>C, 40<sup>0</sup>C and 50<sup>0</sup>C using 3 lots of test strips and three Nova Max Plus meters. Based on the current accelerated stability testing, ketone test strips are stable up to 9 months in a real time environment. Real time shelf life stability testing is ongoing. To demonstrate the shelf-life stability of the Nova Max Plus Ketone control solutions, the sponsor conducted real time testing at 25<sup>0</sup>C and accelerated testing at 40<sup>0</sup>C and 50<sup>0</sup>C using one lot of strips and 3 levels of ketone control solutions. Based on the sponsor's acceptance criteria, the control solutions are stable up to 2 years.

The sponsor provided the value assignment protocols for ketone control solutions. Values are assigned by assaying the control materials multiple times on multiple meters. The mean values are obtained and ranges are assigned based upon the results obtained. Target values are provided in the labeling.

The shelf life and traceability studies for blood glucose measurement for strips and controls were addressed in the sponsor's predicate device (Nova Max Blood Glucose Monitor –k070255) that uses the same glucose test strips.

d. *Detection limit:*

The sponsor conducted Limit of Detection (LOD) studies following CLSI EP-17-A (Protocols for Determination of Limit of Detection and limit of Quantitation, Approved Guideline). Five samples containing no ketones were tested 100 times to determine the limit of blank. Non-parametric analysis yielded a limit of blank of 0.06. To determine the LOD, a low sample (0.20) was tested 100 times. The equation,  $LOD = LOB + 1.6494 * SD$  yielded a LOD of 0.093.

The limit of detection for blood glucose measurement was addressed in the sponsor's predicate device (Nova Max Blood Glucose Monitor –k070255) that uses the same glucose test strips.

e. *Analytical specificity:*

Following CLSI EP7 guidelines, the sponsor tested a total of 21 substances that may interfere with  $\beta$ -ketone measurements. Three ketone spiked blood samples were prepared (ketone concentrations 0-0.8mM, 2.0-3.5mM and 5.0-7.0mM) for each potentially interfering substance. The concentrations of the potential interference compounds spiked into samples covered the low and high end of therapeutic range and the toxic range. One sample was assayed for each concentration using five monitors. The sponsor concluded that the results demonstrated no significant interference from the substances tested. The results for each interfering substance are given in the table below:

Substance	Interference concentration (mg/dl)	Ketone Concentration 0-0.8 mM			Ketone Concentration 2.0-3.5 mM			Ketone Concentration 5.0-7.0 mM		
		S.D	Bias	Ref.	CV%	Bias %	Ref.	CV%	Bias %	Ref.
acetaminophen	0	0.04	0.0	0.18	4.9	7.2	2.5	4.7	1.0	6.1
	20	0.04	0.0		1.7	9.2		4.3	4.9	
Acetone	0	0.04	-0.04	0.26	2.9	6.7	2.7	3.5	-0.9	6.4
	10	0.0	-0.03		4.0	5.2		3.7	-1.3	
acetoacetate	0	0.0	-0.03	0.13	2.7	7.6	2.9	4.3	-1.6	6.4
	10	0.0	-0.01		3.6	7.9		4.0	2.0	
ascorbic acid	0	0.05	-0.02	0.36	4.1	10.4	2.5	5.3	1.3	6.3
	20	0.05	-0.06		6.0	-3.3		5.0	-6.8	
Bilirubin	0	0.05	0.04	0.28	6.7	6.2	2.9	4.12	12.8	6.4
	10	0.04	0.0		4.8	0.6		3.9	10.9	
Captopril	0	0.05	-0.03	0.29	3.2	-3.0	2.7	1.5	-4.3	6.1
	10	0.0	-0.02		6.9	0.0		3.8	4.9	
Cholesterol	0	0.04	0.02	0.4	6.5	6.7	2.4	4.0	4.5	6.2
	500	0.07	0.10		5.2	8.0		6.2	7.0	
Creatinine	0	0.0	0.0	0.1	3.8	-7.1	2.8	4.0	8.7	5.5
	6	0.04	0.02		3.2	-9.7		3.6	8.6	
Dopamine	0	0.05	-0.06	0.3	4.8	0.7	2.7	5.6	-1.2	6.5
	2	0.4	0.02		5.6	7.7		6.1	2.0	
Ephedrine	0	0.08	-0.02	0.5	6.2	-2.4	2.5	4.0	-2.1	5.6
	0.9	0.05	0.04		3.4	-0.8		7.2	-4.4	
Glucose	0	0.04	-0.02	0.2	3.6	-3.4	2.9	4.0	-1.2	6.8
	900	0.05	-0.04		5.5	2.2		3.8	2.2	
Ibuprofen	0	0.04	-0.02	0.3	6.8	-1.5	2.7	2.8	3.0	6.1
	48	0.05	0.04		2.1	2.3		7.9	2.3	
L-dopa	0	0.04	0.02	0.1	1.8	0.8	2.4	5.1	1.8	5.6
	100	0.05	0.06		4.8	5.0		6.0	1.4	
Methyl dopa	0	0.04	-0.08	0.3	7.1	2.2	2.7	2.6	2.5	6.3
	1	0.04	-0.02		4.9	-0.7		4.1	-1.3	
N-acetylcysteine	0	0.04	0.02	0.1	4.0	-7.4	2.7	5.4	-5.6	6.1
	10	0.0	0.0		4.5	-3.2		3.6	-5.1	
Salicylate	0	0.04	-0.02	0.1	2.1	-8.3	2.9	6.9	10.2	5.5
	30	0.04	-0.02		4.3	-9.0		5.4	8.4	
Tetracycline	0	0.04	-0.02	0.1	2.2	-9.3	2.8	3.7	4.2	5.7
	30	0.04	-0.08		4.4	-4.6		3.7	8.1	
Tolazamide	0	0.0	0.0	0.3	4.7	-3.7	2.7	4.0	-4.9	6.1
	15	0.0	0.0		3.4	6.4		3.9	4.8	
Tolbutamide	0	0.07	0.0	0.2	4.7	-3.7	2.7	2.9	-0.3	6.1
	45	0.0	0.0		4.6	-5.4		4.8	5.3	
Triglycerides	0	0.04	-0.02	0.1	8.5	0	3.0	3.9	2.1	6.8
	750	0.05	-0.04		8.1	9.6		4.1	4.5	
Uric acid	0	0.05	-0.06	0.3	6.2	2.9	2.8	6.2	5.4	5.6
	20	0.0	0.0		5.7	-5.0		5.7	9.3	

The interference studies for blood glucose measurement were addressed in the sponsor’s predicate device (Nova Max Blood Glucose Monitor –k070255) that uses the same glucose test strips.

The sponsor evaluated the effect of hematocrit between 20% and 64% in whole blood samples at 4 levels of ketones (0.1-0.8, 2-3, 4-5, and 6-8). Duplicates of each were assayed on five Nova Max Plus monitors using two lots of test strips. A reference value was assayed on a plasma sample remaining from each blood sample using reference laboratory reagents. The bias for all samples tested was less than 11%. The claimed hematocrit range is 25% to 60% for both glucose and ketones.

The interference studies for blood glucose measurement were addressed in the sponsor’s predicate device (Nova Max Blood Glucose Monitor –k070255) that uses the same glucose test strips.

The altitude studies for blood glucose measurement were addressed in the sponsor’s predicate device (Nova Max Blood Glucose Monitor –k070255) that uses the same glucose test strips.

f. *Assay cut-off:*  
Not Applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

The sponsor conducted accuracy studies to assess the performance of Nova Max Plus Blood Glucose and  $\beta$ -Ketone Monitor system in the hands of the consumer (subject) and a trained laboratorian relative to a standard measurement using an enzymatic spectroscopy reference method. Three lots of Nova Max Blood ketone strips were randomized across 182 (sample range: 0.1 – 7.5 mmol/L) subjects with Type1 and Type 2 diabetes. Testing was done by the users using finger tip lancing only. Results of the linear regression analysis in reference to the user results are summarized in the table below.

User evaluation Fingertip (N=182)	Reference method	Laboratorian
slope	0.9896	1.01
y=intercept	0.041	0.0038
R square	0.996	0.996

The sponsor’s alternative site testing (palm and forearm) is limited to the glucose measurement only. The accuracy studies for blood glucose measurement were addressed in the sponsor’s predicate device (Nova Max Blood Glucose Monitor –k070255) that uses the same glucose test strips. However, the sponsor conducted additional method comparison studies using

blood samples to demonstrate the accuracy for glucose measurements are maintained in the new device.

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):*  
Not Applicable.

4. Clinical cut-off:  
Not Applicable

5. Expected values/Reference range:

Based on the published literature, the sponsor included the following Expected Values for normal glucose levels in their strip labeling:

Status	Plasma glucose range for people without diabetes (mg/dL)
Before meals	70-110
2 hours after meals	<120

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Source: American Diabetic Association Clinical Practice Recommendations 2003

The expected value for ketones is less than 0.6 mmol/L. (American journal of Clinical pathology 107: 333-358. 1997).

**N. Instrument Name:**

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

**O. System Descriptions:**

1. Modes of Operation:

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

2. Software:

FDA reviewed applicant's Hazard Analysis and software development processes for glucose measurement in k070255. Additionally, in this submission, the sponsor provided data to support the added new features for ketone measurements.

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 capillary whole blood from the finger for ketone measurement and finger, the palm, and the forearm for glucose measurement only. Since the whole blood sample is applied directly to the test strip, there are no special handling or storage issues.

5. Calibration:

A single calibration code is programmed into the meters at the time of manufacturing and no user Input is required

6. Quality Control:

Three glucose control solutions and three ketone control solutions at three different concentrations to be run with this device are available. The user is referred to the troubleshooting section of the owner's manual if control results fall outside these ranges.

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

Not applicable

**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.