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

A. 510(k) Number:
k112638

B. Purpose for Submission:
New device

C. Measurand:
Capillary whole blood glucose

D. Type of Test:
Whole blood glucose concentration through a quantitative amperometric assay (GDH-FAD)

E. Applicant:
Nova Biomedical Corporation

F. Proprietary and Established Names:
Nova Max One Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1345 Glucose Test System
   21 CFR 862.1660, Quality Control Material (assayed and unassayed)

2. Classification:
   Class II (assay) and Class I, reserved (controls)

3. Product code:
   NBW, Blood Glucose Test System, Over-the-Counter
   LFR, Glucose Dehydrogenase
   JJX, Single (specified) analyte controls (assayed and unassayed)

4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See indication for use below.

2. Indication(s) for use:
   The Nova Max One Blood Glucose Monitor is intended to be used for the quantitative measurement of glucose in 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 neonates.

The Nova Max One Blood Glucose Test Strips are intended for use only with the Nova Max One Blood Glucose Monitor for quantitative tests. The Glucose monitor is intended to quantitatively measure glucose (sugar) in fresh capillary whole blood obtained from the finger tip or alternative site testing (AST) on the forearm. AST can be used only during steady-state blood glucose conditions. The Glucose Monitor is calibrated to provide plasma equivalent results to laboratory methods. The Nova Max One Blood Glucose Test Strips are for testing outside the body (in vitro diagnostic use only). The monitor should only be used by a single user in the home and should not be shared by users. It is not intended for the diagnosis of or screening for diabetes, and it is not intended for use on neonates.

Nova Max Control Solutions are intended for use with the Nova Max Blood Glucose Monitoring Systems as a quality control check to verify the accuracy of blood glucose test results. There are three levels of controls, (Levels 1, 2, 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 One Blood Glucose Monitor

I. Device Description:

The Nova Max One Glucose Monitoring System Kit contains the following:

- Nova Max One Blood Glucose Monitor
- 10 Nova Max One Test Strips
- Battery (3V Cell)
- Nova Max One Quick Reference Guide

- Nova Max One Owner's Guide
- Nova Max One Log Book
- Nova Sureflex Lancing Device with Alternate Site Testing Cap
- 10 Lancets, 30 gauge
- Nova Max Glucose Control Solution, Level 2
- Warranty Card
- Day Case

Offered separately:

- Nova Max Glucose Control Solutions: Level 1, 2 and 3
- 50 Nova Max One Test Strips (2 vials of 25)

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Nova Max Blood Glucose Monitor

2. Predicate k number(s):
   k070255

3. Comparison with predicate:

Item	Nova Max One Blood Glucose Monitor System	Nova Max Blood Glucose Monitor System (k070255)
Similarities		
Intended use	Intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. It is intended for self testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control.	Same
Operating principle	Coulometric Electro-chemical sensor	Same
Test range	20 to 600 mg/dL	Same
Hematocrit	25% to 60%	Same
Coding	None	Same
Control solutions	3 level liquid control solutions	Same
Differences		
Enzyme	Glucose Dehydrogenase-FAD	Glucose Oxidase
Sample size	0.4 µL	0.3 µL
Sample sites	Fingertip and forearm	Fingertip, forearm and palm
Analysis time	4 seconds	5 seconds
Intended users	Over-the-counter, Single patient use	Over-the-counter and healthcare professional

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

None were referenced

L. Test Principle:

The Nova Max One Glucose Monitor measures glucose electrochemically. The glucose biosensor is capable of recognizing the glucose present in whole blood or control solutions by virtue of the glucose specificity of the enzyme glucose dehydrogenase (GDH) present on the glucose test strip. The electrons liberated by this reaction are transferred via a co-factor and mediator to the meter where they are read as a small electrical current. The current is integrated over the analysis time to generate charge which is directly proportional to the level of the glucose in the applied sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Day-to-day precision was evaluated using 3 levels of aqueous glucose control solutions (33-53 mg/dL, 77-104 mg/dL and 232-313 mg/dL), 3 lots of test strips and 2 meters. Each level was tested twice daily for 20 days on each meter for a total of 80 tests per glucose level per lot of test strips. The results are summarized below:

Day-to-day:

Lot	Mean (n=80)	SD	Mean (n=80)	CV%	Mean (n=80)	CV%
1	43.0	2.0	91.6	3.0	272.3	2.3
2	43.1	1.8	91.4	2.8	275.6	2.7
3	43.0	2.6	91.5	3.1	270.2	1.9

The within-run precision study was performed using venous whole blood samples spiked to create 5 concentration levels of blood glucose (50-100 mg/dL, 100-200 mg/dL, 200-300 mg/dL, 300-400 mg/dL and 500-600 mg/dL). Three lots of test strips and 5 meters were used in the study, with 4 tests performed on each meter for a total of 20 tests per blood glucose level per test strip lot. The results are summarized below:

Within run

Lot	Mean (n=20)	SD	Mean (n=20)	CV%	Mean (n=20)	CV%	Mean (n=20)	CV%	Mean (n=20)	CV%
1	71.9	3.6	158.0	2.8	234.5	2.9	337.1	4.0	548.7	2.5
2	73.1	2.9	157.8	3.6	234.5	3.2	342.2	2.6	540.7	3.0
3	73.0	3.7	157.9	3.2	235.5	2.5	338.6	3.1	547.4	2.2

The sponsor also evaluated the within-run precision of the device using 3 levels of aqueous glucose control solutions (33-53 mg/dL, 77-104 mg/dL and 232-313 mg/dL). The results are summarized below:

Within-run

Lot	Mean (n=20)	SD	Mean (n=20)	CV%	Mean (n=20)	CV%
1	42.5	2.3	92.5	2.6	272.2	1.8
2	43.1	2.4	92.5	2.3	270.2	2.2
3	42.5	2.7	91.7	2.3	270.8	2.2

b. *Linearity/assay reportable range:*
The sponsor performed linearity studies using venous whole blood samples with 7 levels of blood glucose (15-30 mg/dL, 40-60 mg/dL, 80-110 mg/dL, 180-210 mg/dL, 280-310 mg/dL, 480-510 and 570-620 mg/dL) covering the measuring range (18 to 605 mg/dL) of the proposed device. Three lots of test strips and 5 meters were used in the study with 2 tests per glucose level per lot performed on each meter. The YSI-2300 glucose analyzer was used as the reference method. Linear regression analysis for each test strip lot is summarized below:

Lot 1 $y = 1.0023x – 0.2922$, $r^2 = 0.9995$
Lot 2 $y = 1.0012x – 0.2569$, $r^2 = 0.9997$
Lot 3 $y = 1.0007x – 0.3039$, $r^2 = 0.9997$

The sponsor claims that the device is linear from 20 - 600 mg/dL. The measuring range of the device is 20 - 600 mg/dL.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
The glucose measurements are traceable to D-glucose (NIST SRM 917B).

The control solutions are identical in composition to those cleared under k070255. The only difference is that they have been renamed to Nova Max Control Solutions (Levels 1, 2, 3).

Stability Studies: The sponsor performed stability studies for the test strips. The protocols and acceptance criteria were reviewed and found to be acceptable. The sponsor claims a closed-vial (shelf life) of 24 months when strips are stored at 15 to 30 °C and open-vial stability of 90 days when strips are stored at 15 to 30 °C.

d. *Detection limit*:
See linearity study.

e. *Analytical specificity:*
The sponsor performed interference studies using spiked venous whole blood samples at three glucose concentrations (50 – 100, 250 – 350 and 450 - 550 mg/dL). Each potential interfering substance was evaluated at 2 concentrations at each glucose level along with the corresponding control (un-dosed) sample. Each sample was tested once on 5 meters. The sponsor defined no interference if the bias (difference between the dosed sample and

the control sample) was ≤ 10%. The results of the study are summarized below:

Substance	Maximum Test Concentration (mg/dL)	Concentration at which interference was observed (mg/dL)
Acetaminophen	10	none
Ascorbic Acid	5	none
Bilirubin	15	none
Cholesterol	500	none
Captopril	20	none
Creatinine	6	none
Dopamine	2	none
Ephedrine	5.4	none
D(+) Galactose	300	none
Ibuprofen	48	none
L-Dopa	5	none
Maltose	300	none
Methyl Dopa	1	none
N-acetylcysteine	10	10
Salicylate	30	none
Tetracycline	30	none
Tolazamide	5	none
Tolbutamide	45	none
Triglyceride	750	none
Uric Acid	20	10.5

The sponsor included the following limitation in the labeling:
Therapeutic levels of n-acetylcysteine and elevated uric acid may affect results.

f. Assay cut-off:
Not applicable

2. Comparison studies:

a. Method comparison:
The sponsor conducted a combined accuracy and consumer study. Testing was performed with trained operators and a total of 201 lay-users. Each lay user participant performed one finger lancing and one forearm lancing and tested their blood on the proposed device following the instructions of the proposed device's labeling. A trained operator then performed a second fingerstick and a forearm lancing and tested the blood on the proposed device. Venous blood was also collected and measured on a YSI analyzer. The total range of samples tested was 39 to 569 mg/dL. Linear regression results are presented below:

Fingerstick:

	Slope	Intercept	R
Professional vs YSI	0.963	1.917	0.99565
Lay user vs. YSI	0.966	1.562	0.99472

Forearm :

	Slope	Intercept	R
Professional vs YSI	0.957	0.318	0.98848
Lay user vs. YSI	0.977	0.011	0.98810

The study results met the ISO 15197 accuracy criteria where ninety-five percent (95%) of the individual glucose results fell within ±15mg/dL of the YSI results at glucose concentrations <75mg/dL and within ±20% at glucose concentrations ≥75mg/dL.

The following tables summarize the fingerstick data:

For glucose concentrations <75 mg/dL

	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Professionals	16/26 (62%)	25/26 (96%)	26/26 (100%)
Lay user	16/26 (62%)	24/26 (92%)	26/26 (100%)

For glucose concentrations ≥ 75 mg/dL

	within ± 5 %	within ± 10 %	Within ± 15 %	within ± 20 %
Professionals	95/175 (55%)	160/175 (91%)	174/175 (99%)	175/175 (100%)
Lay user	100/175 (57%)	164/175 (94%)	175/175 (100%)	175/175 (100%)

The following tables summarize the forearm data:

For glucose concentrations <75 mg/dL

	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Professionals	8/26 (31%)	22/26 (85%)	26/26 (100%)
Lay user	10/26 (38%)	22/26 (85%)	26/26 (100%)

For glucose concentrations ≥ 75 mg/dL

	within ± 5 %	within ± 10 %	Within ± 15 %	within ± 20 %
Professionals	74/175 (42%)	130/175 (74%)	155/175 (89%)	168/175 (96%)
Lay user	74/175 (42%)	128/175 (73%)	165/175 (94%)	172/175 (98%)

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:
In the labeling the sponsor provides the following expected values and reference citation:

The normal fasting adult blood glucose value for a person without diabetes is <100 mg/dL. One to two hours after meals normal blood glucose levels should be less than 140 mg/dL.

Reference: American Diabetes Association, Clinical Practice Recommendations. (2010). Diabetes Care, Vol 33, Supplement 1, p S1-S100.

N. Instrument Name:
Nova Max One Blood Glucose Monitor

O. Systems Descriptions:

1. Modes of Operation:
Each test strip is single use and must be replaced with a new strip for additional readings.

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 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:
   Fresh capillary whole blood testing only.

5. Calibration:
   Calibration is performed by the manufacturer and does not need to be performed by the end user. The meter does not require coding.

6. Quality Control:
   The sponsor has three levels of control solutions (level 2 control solution is included with the kit). When a test strip is inserted into the meter, each control can be measured by following the instructions for "Running Control Solution" provided in the user's manual. An acceptable range for each control level is printed on the test strip vial label. If the test results fall outside the range printed on the test strip vial, the user is instructed to contact Customer Service (available 24 hours a day, 7 days a week).

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

Infection control: This device is intended for single-patient use. Disinfection efficacy studies (viral efficacy studies) were performed by an outside service to evaluate the virus elimination effectiveness of disinfecting wipes in preventing the spread of bloodborne pathogens, particularly hepatitis B virus (HBV). Specifically, Clorox Germicidal Wipes (EPA registration #67619-12) were validated demonstrating complete inactivation of live virus. The sponsor also performed robustness studies and demonstrated that there was no change in the performance or the external materials of the meters after 1095 cleaning and disinfection cycles designed to simulate 3 years of weekly cleaning and disinfecting. The sponsor also performed robustness studies and demonstrated that there was no deterioration in the performance or the external materials of the lancing device following 300 cleaning and disinfection cycles designed to simulate 3 years of weekly cleaning and disinfecting. Labeling has been reviewed for adequate instructions in validated cleaning and disinfection procedures.

Hematocrit Study:
A study to evaluate the effect of hematocrit was conducted on samples with 4 glucose concentrations (50-80 mg/dL, 100-150 mg/dL, 250 to 350 mg/dL and 450-550 mg/dL) at 11 hematocrit levels from 20% to 70% (with hematocrit increasing in 5% increments). Each glucose level/hematocrit combination was tested in duplicate on 5 meters using 3 lots of test strips. Results of samples at each hematocrit level were compared to the corresponding YSI value. The sponsor claims a hematocrit range of 25 to 65%. The study protocol and data were found adequate to support the sponsor's claim.

Altitude study: An altitude study was performed in an altitude simulation chamber with venous blood samples with 3 glucose concentrations (50-100 mg/dL, 200-300

mg/dL and 450-550 mg/dL) using 3 meters and 3 lots of test strips. The study protocol and data were reviewed and found to be adequate. The sponsor claims that an altitude up to 10,000 feet does not affect the test results of the proposed device.

Sample volume study: Sample volume studies were conducted with venous blood samples (45-65 mg/dL, 80-120 mg/dL, 200-250 mg/dL and 450-550 mg/dL) spanning the measuring range of the proposed device using 4 meters and 3 lots of test strips. The sponsor evaluated the following sample volumes: 0.30µl, 0.35µl, 0.40µl, 0.45µl and 0.50µl. The study protocol and data across the entire measuring range were provided and found adequate to support the sponsor's claim that a minimum of 0.40µl of sample volume are required for this system.

Test system operating conditions: Temperature and humidity studies were conducted with venous blood samples (50-100 mg/dL, 200-300 mg/dL and 450-550 mg/dL) and aqueous control solutions (levels 1, 2 and 3) spanning the measuring range of the proposed device using 5 meters and 3 lots of test strips. The sponsor evaluated the following environmental conditions, 5ºC and 10% relative humidity (RH), 25ºC and 50% RH and 50ºC and 90% RH. A subsequent study was performed with venous blood samples (45-65 mg/dL, 75-100 mg/dL, 200-300 mg/dL and 450-550 mg/dL) and aqueous control solutions (level 1, 2 and 3) spanning the measuring range of the proposed device using 5 meters and 3 lots of test strips. The sponsor evaluated the following environmental conditions, 5ºC and 90% RH, 25ºC and 50% RH and 50ºC and 10% RH. The study protocol and data across the entire measuring range were provided and found to be adequate.

Electromagnetic compatibility (EMC) and electrical safety testing: EMC testing was evaluated and certified by The Compliance Management Group.

Readability assessment: The sponsor performed a readability assessment of the labeling and states that the owner's guide, strip insert and control insert are written at the 8th grade level or below based on Flesch-Kincaid Readability Assessment.

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.