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

A. 510(k) Number:

k122435

B. Purpose for Submission:

Extension of indication for use to include more sample types (add venous, arterial whole blood) and multiple-patient use to a previously cleared single–patient use meter

C. Measurand:

Venous, arterial and capillary whole blood glucose

D. Type of Test:

Quantitative, Amperometric method, Glucose dehydrogenase (FAD)

E. Applicant:

Nova Biomedical Corporation

F. Proprietary and Established Names:

Nova One Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LFR – Glucose dehydrogenase, glucose	Class II	21 CFR § 862.1345	75-Chemistry
NBW, Blood Glucose Test System, Over-the-Counter	Class II	21 CFR § 862.1345	75-Chemistry
JJX – Quality Control material	Class I, reserved	21 CFR § 862.16	75-Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The Nova One Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in venous, arterial and fresh capillary whole blood from the finger and forearm. It is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in a professional healthcare setting as an aid to monitor the effectiveness of diabetes control program. This system should only be used with single-use, auto-disabling lancets. The Nova One Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes, and it is not intended for use on neonates. Alternative site testing on the forearm should be used only during steady-state blood glucose conditions.

   Nova One Blood Glucose Test Strips are for use with the Nova One Blood Glucose Monitors for quantitatively measuring glucose in venous, arterial and fresh capillary whole blood from the finger and forearm.

   Nova Max Control Solutions are intended for use with the Nova Max, Nova Max One and Nova One 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 prescription use and OTC use.
   - Not intended for the diagnosis of 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.
   - The performance of this system has not been evaluated on the critically ill.
   - Alternative site testing should not be used for calibrating continuous glucose monitors, nor for insulin dosing calculations

4. Special instrument requirements:

   Nova One Blood Glucose Monitor

I. Device Description:

The Nova One Glucose Monitoring System Kit contains the following:

- Nova One Blood Glucose Monitor
- 10 Nova One Test Strips
- Battery (3V Cell)
- Nova One Blood Glucose Monitor Quick Reference Guide
- Nova One Blood Glucose Monitor Owner's Guide
- Nova One Log Book
- 5 Nova Safety Lancet, 28g (Single Use Disposable Lancing Device)
- 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 One Test Strips (2 vials of 25)
- Nova Safety Lancets, 28g,Qty 4000
- Nova Safety Lancets, 23g,Qty 4000

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Nova Max One Blood Glucose Monitoring System

2. Predicate K number(s):

   k112638

3. Comparison with predicate:

Item	**Candidate device** Nova One Blood Glucose Monitoring System	**Predicate device** Nova Max One Blood Glucose Monitoring System (k112638)
Intended Use/Indications for Use	Same	For the measurement of glucose in whole blood.
	Prescription use	Over-the-counter use (OTC)

	Multiple patient professional use	Single patient home use
	Capillary whole blood samples from fingertip and forearm Venous or arterial whole blood samples (lithium or sodium heparin tubes)	Capillary whole blood samples from fingertip and forearm
Meter	Identical meter under new trade name Nova One	Nova Max One
Strips	Identical strips under new trade name Nova One	Nova Max One
Control solutions	Same	Nova Max Glucose Control Solutions Level 1, 2 and 3

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

IEC 60601: Medical electrical equipment-Part 1-2: general requirements for safety-. collateral standard: Electromagnetic compatibility.

EN55011: Limits and methods of measurement of radio disturbance characteristics of industrial, scientific, and medical RF equipment, 1, B

IEC61010: Safety requirements for electrical equipment for measurement, control, and laboratory use-part 1: General requirements

L. Test Principle:

The Nova 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 (FAD) 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. <u>Analytical performance:</u>

The meter, strips and control solutions are identical to those cleared under k112638. The sponsor uses the same analytical claim for the current test system and refers to the predicate 510 (k) for the respective studies.

a. Precision/Reproducibility:

Same as established in k112638.

b. Linearity/assay reportable range:

The measuring range of the device is 20-600 mg/dL based on studies conducted in k112638.

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

Traceability:

Traceable to NIST SRM 91, dry D-glucose.

Value assignment:

The control solutions are previously cleared under k112638.

Stability:

As established in k112638. 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.

This information is provided in the labeling of the test strips and control materials.

d. Detection limit:

See *Linearity/assay reportable range* above in b.

e. *Analytical specificity:*

As established in k112638. The sponsor has provided the following statements in the labeling:

- Cholesterol up to 500 mg/dL or triglyceride up to 750 mg/dL do not significantly affect results.
- Therapeutic levels of n-acetylcysteine and elevated uric acid may affect results.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with reference method (*YSI*):

The system accuracy on finger stick samples was evaluated in the predicate k112638.

To evaluate system accuracy on venous and arterial samples, healthcare professionals tested three lots of Nova One test strips on a total of 160 venous and arterial samples collected in Lithium Heparin tubes. Among the samples tested, 10 of the 29 arterial samples and 6 of 23 venous samples were spiked to ensure adequate coverage of the high reportable range.

The distribution of the sample glucose concentrations is specified in the table below.

Sample description:

Glucose Concentration (mg/dL)	Number of samples	
	Arterial Blood	Venous Blood
< 50	11	6
50 - 80	33	26
81 - 120	36	50
121 - 200	37	39
201 - 300	14	16
301 - 400	13	13
> 400	16	10
Total	160	160

ISO 15197 Acceptance Criteria:

95% of individual glucose results shall fall within ±15mg/dL of reference method at glucose concentrations < 75mg/dL and within ± 20% at glucose concentrations ≥ 75mg/dL.

Result Summary:

Arterial Blood Glucose < 75 mg/dL (34 samples)

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Lot 1	26/34 (76.5%)	32/34(94.1%)	34/34 (100.0%)
Lot 2	27/34 (79.4%)	34/34 (100.0%)	34/34 (100.0%)
Lot 3	23/34 (67.6%)	34/34 (100.0%)	34/34 (100.0%)

Arterial Glucose ≥ 75 mg/dL (126 Samples)

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
Lot 1	76/126 (60.3%)	116/126 (92.1%)	122/126 (96.8%)	125/126 (99.2%)
Lot 2	81/126 (64.3%)	115/126 (91.3%)	120 of 126 (95.2%)	126/126 (100.0%)
Lot 3	80/126 (63.5%)	114/126 (90.5%)	121/126 (96.0%)	125/126 (99.2%)

Venous Blood Glucose < 75 mg/dL (24 samples)

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Lot 1	19/24 (79.2%)	23/24 (95.8)	24/24 (100.0%)
Lot 2	21/24 (87.5%)	24/24 (100.0%)	24/24 (100.0%)
Lot 3	15/24 (62.5%)	23/24 (95.8)	24/24 (100.0%)

Venous Glucose ≥ 75 mg/dL (136 Samples)

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
Lot 1	95/136 (69.9%)	134/136 (98.5%)	136/136 (100%)	136/136 (100%)
Lot 2	91/136 (66.9%)	126/136 (92.6%)	135/136 (99.3%)	136/136 (100%)
Lot 3	94/136 (69.1%)	129/136 (94.9%)	134/136 (98.5%)	136/136 (100%)

Regression analysis- Nova one versus YSI

Venous Samples	Correlation	Slope	Intercept
Strip Lot 1	0.9976	1.005	0.549
Strip Lot 2	0.9969	0.990	2.484
Strip Lot 3	0.9974	0.993	0.843
Arterial Samples			
Strip Lot 1	0.9976	1.017	-0.674
Strip Lot 2	0.9966	1.015	-0.932
Strip Lot 3	0.9967	1.000	0.988

Conclusion:

The performance of the Nova One glucose meter with Nova One reagent strip on venous and arterial samples meets ISO 15197 accuracy requirement of more than 95% results within the acceptance limits of ±15mg/dL or ±20%.

b. Matrix comparison:

Venous blood samples (N=60) is drawn into Sodium Heparin tubes. Each sample was measured in singlet using 2 Nova One monitors and 3 lots of strips. To obtain samples in the extreme low and high glucose concentration range, 5 native samples were subjected to glycolysis to obtain low glucose results and 5 samples were spiked to obtain high glucose results. The reference glucose concentration was determined using the YSI method. The results are summarized below.

ISO 15197 - Sodium Heparin Sample Distribution Breakdown

Glucose Concentration mg/dL	Recommended Percentage per ISO15197	Blood Samples	
		Number of samples in study	Percentage of samples in study
< 50	5%	5	8.3
51 to 80	10%	11	18.3
81 to 120	20%	16	26.7
121 to 200	30%	12	20.0
201 to 300	20%	7	11.7
301 to 400	10%	6	10.0
> 400	5%	3	5.0

ISO 15197 - Nova One versus YSI, Glucose less than 75 mg/dl

Within ± 5 mg/dl	Within ± 10 mg/dl	Within ± 15 mg/dl
70/78 (89.7%)	78/78 (100%)	78/78 (100%)

ISO 15197 - Nova One versus YSI, Glucose greater than 75 mg/dl

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
230/282 (81.6%)	279/282 (98.9%)	282/282 (100%)	282/282 (100%)

Linear Regression, Nova One versus YSI

Test Strip Lot #	N	Slope	Intercept	Correlation R^2
1	120	0.988	1.006	0.997
2	120	0.998	0.255	0.996
3	120	0.991	0.672	0.996
Pooled Data	360	0.992	0.644	0.997

Conclusion:
Based on the result, the sponsor concluded that the sodium heparin blood glucose results met the ISO 15197 Acceptance Criteria, indicating that the

Nova One Blood Glucose Monitoring System can be utilized to measure blood glucose values accurately when blood samples are collected in sodium heparin anticoagulant blood collection tubes..

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)

   A lay user study on finger stick samples was evaluated in the predicate k112638.

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. (2012). Diabetes Care, Vol 35, Supplement 1, p S11-S63.

N. Instrument Name:

Nova One Blood Glucose Monitor

O. System 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 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, as well as venous and arterial whole blood collected in sodium or lithium heparin tubes. The whole blood sample is applied directly to the test strip by capillary action.

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

The current meter is identical to the predicate meter previously cleared in k112638. Disinfection efficacy studies (viral efficacy studies) were performed and reviewed in the predicate 510(k). Specifically, Clorox Germicidal Wipes (EPA registration #67619-12) were validated demonstrating complete inactivation of live virus.

New robustness study was performed in this submission to support more extensive cleaning and disinfecting cycles in the professional multiple-patient use settings. The sponsor demonstrated that there was no change in the performance or the external materials of the meters after 10950 cleaning and disinfection cycles designed to simulate 70 cycles/week over 3 years professional multiple-patient use. Labeling has been reviewed for adequate instructions in validated cleaning and disinfection procedures.

- Temperature and humidity operating conditions

  The sponsor claims operating temperature from 57^{o}F-104^{o}F (14-40^{o}C) and relative humidity range from 10% to 93% including extreme combinations of temperature and humidity as established in k112638.

- EMC testing

  EMC testing was evaluated and certified by The Compliance Management Group. A test certificate was issued to Nova on June 28, 2012.

- Altitude Study

  The sponsor claims that an altitude up to 10,000 feet does not affect the test results of the proposed device as established in k112638.

- Hematocrit study

  The sponsor claims a hematocrit range of 25 to 65% as established in k112638.

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.