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

A. 510(k) Number:

k100602

B. Purpose for Submission:

New Device

C. Measurand:

Whole venous and arterial blood for lactate

D. Type of Test:

Quantitative, Electromechanical Biosensor using lactate oxidase

E. Applicant:

Nova Biomedical

F. Proprietary and Established Names:
Nova StatStrip Lactate Hospital Meter System

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1450; Lactic acid test system

   21 CFR 862.1660; Quality control material (assayed and unassayed)

2. Classification:
   Class I, meets limitations of exemptions per 21 CFR 862.9 (c)(9); Class I

3. Product code:
   KHP, acid, lactic, enzymatic method
   JJX, single (specified) analyte controls (assayed and unassayed)

4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See Indications for Use below.

2. Indications(s) for use:
   The Nova StatStrip Lactate Hospital Meter System is intended for in vitro diagnostic use by healthcare professionals for multiple patient use in a professional healthcare setting for clinical and for point-of-care usage for the quantitative determination of Lactate (Lac) in fresh venous and arterial whole blood specimens as an aid to evaluate the acid-base status of patients suspected of having lactic acidosis. It is not for use on

capillary blood specimens. It is intended to provide plasma equivalent results to laboratory methods.

Nova StatStrip Lactate Test Strips are intended for use only with the Nova StatStrip Lactate Hospital Meter for quantitative determination of lactate in fresh venous and arterial whole blood specimens. It is not for use on capillary blood specimens. The performance characteristics of the device for lactate measurements on capillary specimens have not been established. Nova StatStrip Lactate Test Strips are for testing outside the body (in vitro diagnostic use only).

Nova StatStrip Lactate Control Solutions are intended for use only with the Nova StatStrip Lactate Hospital Meter and Nova StatStrip Lactate Test Strips as a quality control check to verify the accuracy of blood lactate test results. There are two levels of controls (Level 1 and Level 2).

Nova StatStrip Lactate Linearity Kit solutions are used to check the linearity of the Nova StatStrip Lactate Hospital Meter. There are 4 levels of lactate linearity solutions: Level 1, Level 2, Level 3, and Level 4.

3. Special conditions for use statement(s):
   - Not for use with serum, plasma or capillary whole blood
   - Not for testing on neonates
   - No studies were conducted with patients suspected of having sepsis

4. Special instrument requirements:
   Nova StatStrip Lactate Hospital Meter

I. Device Description:

The Nova StatStrip Lactate Hospital Meter System contains a blood lactate meter, test strips, 2 levels of ready-to-use liquid control solutions (0.3-0.8 mmol/L and 1.3-2.1mmol/L, 4 levels of ready-to-use liquid linearity solutions (0.3-0.8mmol/L, 1.3-2.1mmol/L, 5.0-7.0 mmol/L, 8.5-12.0mmol/L and 14-18.5mmol/L) and a meter docking station.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Arkray KDK Lactate Pro System

2. Predicate 510(k) number(s):
   k980908

3. Comparison with predicate:

Similarities and Differences		
Item	Nova StatStrip Lactate Hospital Meter System	Arkray Lactate Pro System (k980908)
Intended Use	It is intended for in vitro diagnostic use for the measurement of lactate in whole blood as an aid to evaluate the acid-base status of patients suspected of having lactic acidosis.	Same
Settings to be used	Clinical or Point-of-Care settings	Home use and clinical use
Operating Principle	Electromechanical Biosensor Lactate oxidase	Same
Sample Type	Venous or arterial whole blood	Capillary whole blood
Sample volume	0.6 µL	5µL
Measurement range	0.7-20.0 mmol/L	0.8-23.3 mmol/L
Test time	13 seconds	60 seconds
Calibration	Automatic	Calibration strip
Data storage	1000 patient tests 200 QC tests 4000 Operators	20 tests
Weight	360 grams	50 grams

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

- CLSI EP5-A2: Evaluation of Precision Performance of Quantitative Measurement Methods.
- CLSI EP6-A: Evaluation of Linearity of Quantitative Measurement Procedures, A Statistical Approach.
- CLSI EP7-A2: Interference Testing in Clinical Chemistry.
- CLSI EP9-A2: Method Comparison and Bias Estimation Using Patient Samples.
- IEC 61010-1: Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General Requirements
- IEC 61010-2-101: Particular requirements fir in vitro diagnostic (IVD) medical equipment
- IEC 61010-1-2: Medical Electrical Equipment – Part 1-2: General Requirements for Safety- Collateral Standard – Electromagnetic Compatibility – Requirements and Tests

L. Test Principle:

The Nova StatStrip Lactate Test Strips have an electrode that measures lactate. Lactate in the blood sample mixes with the reagent on the test strip to produce an electric current. The amount of current produced is proportional to the amount of lactate in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Day-to-day precision analysis was performed by 9 point-of-care operators using three levels of aqueous controls. For each level of the control solutions, three lots of the strips were tested. Using two Nova StatStrip blood lactate meters, each level of aqueous control solution was run twice daily for twenty days.

Results Summary:

	Strip Lot #1-07062009		Strip Lot #2-07072009		Strip Lot #3-07082009	
	Level 1 (n=80)	Level 2 (n=80)	Level 1 (n=80)	Level 2 (n=80)	Level 1 (n=80)	Level 2 (n=80)
Lactate mM (mean)	1.70	10.4	1.71	10.4	1.69	10.4
CV%	4.8	4.7	5.1	4.7	4.7	3.9
S.D	0.08	0.48	0.09	0.41	0.08	0.40

Within run precision analysis was also performed by 9 point-of-care operators testing five different lactate concentration levels of blood samples (0.7-1.0, 1.5-2.5, 5-6, 10-12 and 15-18 mM) and three levels of aqueous control solutions on three lots of test strips.

Results Summary:

Blood:

Blood Specimens		Lot 07062009 (n=20)	Lot 07072009 (n=20)	Lot 07082009 (n=20)
Level 1	Lactate (mM)	0.78	0.75	0.76
	CV%	7.9	10.2	9.1
	S.D	0.06	0.08	0.07
Level 2	Lactate (mM)	2.15	2.15	2.16
	CV%	4.7	4.7	5.9
	S.D	0.10	0.10	0.13
Level 3	Lactate (mM)	5.59	5.66	5.63
	CV%	2.8	3.3	3.7
	S.D	0.16	0.19	0.21
Level 4	Lactate (mM)	10.64	10.61	10.52
	CV%	3.3	3.3	3.4
	S.D	0.35	0.35	0.36
Level 5	Lactate (mM)	16.96	16.90	16.83
	CV%	1.9	2.0	1.7
	S.D	0.32	0.33	0.29

Controls:

Strip Lots	Lac Control levels	Level 1 (n=20)	Level 2 (n=20)
Lot No 1	Mean (mmol/L)	1.72	10.55
	CV%	2.9	3.5
	S.D	0.05	0.37
Lot No 2	Mean (mmol/L)	1.72	10.51
	CV%	3.4	3.5
	S.D	0.05	0.37
Lot No 3	Mean (mmol/L)	1.71	10.45
	CV%	2.6	3.6
	S.D	0.04	0.38

b. Linearity/assay reportable range:

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The sponsor performed linearity studies using adjusted whole blood samples with 9 different lactate concentration ranges from 0.2 to 21 mM. Duplicate measurements were made with each concentration on 5 meters and three test strip lots. The results were compared to those obtained using the Nova CCX laboratory analyzer as the reference measurement. Linear regression analyses for each test strip lot were as follows:

Lot Numbers	Slope	Y-Intercept	R^2
1	0.9937	0.0415	0.997
2	0.9809	0.0588	0.9981
3	0.9909	0.0061	0.9979

The claimed reportable range of the device is 0.7 to 20mM.

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

Value assignment of the Lactate Control Solution was determined from the mean and standard deviation calculations from a study using 3 lots of test strips and 5 meters. Each lot of test strips was tested 10 times per day over 5 days.

Lactate Control Solution stability was assessed in real time and accelerated studies. The testing supported the claimed closed vial shelf life of 2 years and open vial stability of 90 days when stored at 25-50°C.

Lactate Linearity Solution stability was assessed in real time and accelerated studies. The testing supported the claimed closed vial shelf life of 2 years and open vial stability of 90 days when stored at 25-50°C.

Test strip stability was assessed in real-time and accelerated studies. The testing supported the claimed closed vial shelf life of 2 years and open vial stability of 48 weeks when stored at 25-40°C.

c. *Detection limit:*
The sponsor followed CLSI Guideline EP-17A for determining the limit of detection LOD). First the limit of the blank (LOB) was determined by preparing 5 blank control solution samples and testing each 20 times for a total of 100 measurements. Four low level lactate samples were prepared based on the LOB. The concentration of the samples was 4xLOB. The samples were tested 100 times to calculate the limit of detection (LOD), where LOD = LOB + 1.6494*SD. The calculated LOD for this assay was determined to be 0.12mM. The LOQ was calculated to be 0.32mM.

d. *Analytical specificity:*

The sponsor performed interference studies with spiked venous blood samples at three lactate concentrations (1-3 mM, 4-8 mM, and 12-16 mM) that were prepared and divided into a test (dosed) pool and a control pool. The concentrations of the potential interference compounds spiked into the samples covered the low end of the therapeutic range, high end of therapeutic range and toxic range. The interferents were added to the samples and analyzed using one test strip lot on five meters. The bias between control and dosed samples were calculated for each substance as well as the bias of the dosed sample from the reference for each substance tested. All biases (control to dosed sample and dosed sample to CCX) were within $\pm$ 10%, indicating no significant interference for any of the substances tested.

The following tables lists the interferents tested and the concentrations each were tested at:

	unspiked	**Level 1 (mg/dL)**	**Level 2 (mg/dL)**	**Level 3 (mg/dL)**
Acetaminophen	0	2	10	20
Ascorbic acid	0	0.6	2	10
Bilirubin	0	0.3	1	15
Cholesterol	0	100	200	500
Creatinine	0	0.3	1.2	6
Dopamine	0	0.2	2	10
Ephedrine	0	0.1	0.3	0.9
D-Glucose	0	100	300	900
Ibuprofen	0	6	16	48
L-dopa	0	0.5	2	5
Methyl dopa	0	0.1	0.5	1
Salicylate	0	2	10	30
Tetracycline	0	5	10	30
Tolazamide	0	0.5	5	15

Tolbutamide	0	2.5	1.5	45
Triglycerides	0	10	250	750
Uric Acid	0	2	10	20

e. Assay cut-off:
Not Applicable

2. Comparison studies:
a. Method comparison with predicate device:

The sponsor conducted a method comparison study at 3 clinical sites. Testing was conducted by 13 point-of-care personnel on a total of 106 patient venous samples ranging from 1.6 – 15.9 mmol/L lactate and 106 patient arterial samples ranging from 0.8 – 13.4 mmol/L lactate and compared to the Nova Biomedical StatProfile pHOx Plus L laboratory assay.

Linear regression results are presented below:

venous $y = 1.041x - 0.36$, $r^2 = 0.978$, $x = 106$
arterial $y = 1.114x - 0.70$, $r^2 = 0.979$, $x = 106$

b. Matrix comparison:
Venous blood samples were drawn into tubes containing lithium heparin and sodium heparin and spiked to concentrations of 0.8-1.5, 3.0-4.0, 6.0-8.0, 9-11, 13-16 and 17-20 mM lactate. Each concentration was assayed 2 times on 5 Nova StatStrip Lactate Hospital Meters and the results compared to the Nova CCX laboratory analyzer as the reference measurement. Linear regression results are presented below:

Lithium heparin $y = 0.987x + 0.033$, $r2 = 0.998$, $x = 60$
Sodium heparin $y = 1.006x + 0.013$, $r2 = 0.998$, $x = 60$

All study results fell within ±10% of the reference results.

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 adult blood lactate range (referenced from Tietz Textbook of Clinical Chemistry) is 0.7 – 2.5 mmol/L

N. Instrument Name:

Nova StatStrip Lactate Hospital Meter

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 __X__ or No _____.

   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 _____

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

3. Specimen Identification:

   The meter has a built-in barcode scanner. Patients IDs and test strip and quality control lot numbers may be scanned into the meter.

4. Specimen Sampling and Handling:

   This device is intended to be used with arterial and venous whole blood, which can be applied to the test strip with a pipette or syringe.

5. Calibration:

   No calibration is required by the user.

6. Quality Control:

   The sponsor provides three levels of control solutions for use with the device. An acceptable range for each control level is printed on the control solution vial label.

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

Hematocrit Study:
A study to evaluate the effect of hematocrit was conducted on samples with 4 lactate concentrations (0.5-1.5, 2.5-3.5, 8-10, and 14-18mM) at 4 hematocrit levels (24, 40, 50, and 65%). Each lactate level/hematocrit combination was tested 10 times on 5 meters. Results of samples at each hematocrit level were compared to samples with the same lactate concentration at normal (40%) hematocrit as well as to the corresponding value from the laboratory assay. All results were within $\pm$ 15% of the reference which supports the claimed hematocrit range of 24-65%.

Oxygen/Altitude study:
To evaluate the effect of oxygen on the lactate measurement and to validate that the device can work at altitude up to 15,000 feet, four levels of oxygen concentrations of blood samples (20 -40 mmHg, 80 -100 mmHg, 130-160 mmHg and 190-220 mmHg), were each tested with four concentration levels of lactate (0.3-1.0, 2.5-3.5, 9-11, and 15-18 mM) on five meters with three lots of test strips. All results were within $\pm$ 10% of the laboratory assay result. The normal pO_2 of capillary blood at altitude of 15,000 ft is about 32 mmHg while pO_2 range at sea level is between 90 to 120 mmHg. The constant lactate results measured at 20-200 mmHg indicate the suitability of the device for measurement up to 15,000 ft.

Temperature and humidity studies:
Temperature and humidity studies were conducted that demonstrated that the devices can be used at temperatures of 5 to 40°C and at a relative humidity of 10 to 90%.

Disinfection and Robustness studies: The Nova StatStrip Lactate Hospital Meter System is intended for multiple patient use. Disinfection efficacy studies were performed on the meter materials by an outside commercial testing service demonstrating complete inactivation of live Hepatitis B virus with Clorox Germicidal Wipes (EPA Reg. No: 67619-12. The sponsor also demonstrated that there was no change in device performance or in the external materials of the meter after 10,950 cleaning and disinfection cycles with the Clorox Germicidal Wipes. This testing was designed to simulate 3 years of usage at 10 patient samples per day. Labeling has been reviewed for adequate instructions in validated cleaning and disinfection procedures.

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.