

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

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

k131013

**B. Purpose for Submission:**

Modification of previously cleared device to include an optional ketone test alert and auto control detection.

**C. Measurand:**

FOCUS Blood Glucose Monitoring System: Glucose in fresh capillary whole blood obtained from the fingertip or forearm

FOCUS Pro Blood Glucose Monitoring System: Glucose in venous and arterial whole blood and in fresh capillary whole blood obtained from the fingertip or forearm.

**D. Type of Test:**

Quantitative amperometric assay (GDH-FAD)

**E. Applicant:**

Nova Biomedical Corporation

**F. Proprietary and Established Names:**

FOCUS Blood Glucose Monitoring System  
FOCUS Pro Blood Glucose Monitoring System

**G. Regulatory Information:**

Product Code	Classification	Regulation Section	Panel
NBW	Class II	21 CFR§ 862.1345, Glucose Test System	Clinical Chemistry (75)
LFR	Class II	21 CFR§ 862.1345, Glucose Test System	Clinical Chemistry (75)
JJX	Class I, reserved	21 CFR § 862.1660, Quality control material	Clinical Chemistry (75)

## H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

The FOCUS Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood obtained from the fingertip or forearm. Intended to be used by a single-patient and should not be shared. Intended for self-testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. Alternative site testing on the forearm can be used only during steady-state blood glucose conditions. Not intended for the diagnosis of or screening for diabetes, and not intended for use on neonates.

FOCUS Blood Glucose Test Strips are used only with FOCUS Meters to quantitatively measure whole blood glucose in fresh, human capillary whole blood taken from the fingertip or forearm.

FOCUS Control Solution is for use with FOCUS and FOCUS PRO Meters and Test Strips as a quality control check to verify that the meter and test strip are working together properly, and that the test is performing correctly.

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

FOCUS PRO Blood Glucose Test Strips are used only with FOCUS PRO Meters for the quantitative measurement of glucose in venous and arterial whole blood and in fresh capillary whole blood taken from the fingertip or forearm..

3. Special conditions for use statement(s):

FOCUS Blood Glucose Monitoring System  
FOCUS Pro Blood Glucose Monitoring System

The FOCUS Blood Glucose Monitoring System

- For Over-the-Counter use
- Not for neonatal use

- Not for screening or diagnosis of diabetes mellitus
- Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients
- Alternative site testing (AST) can be used only during steady-state blood glucose conditions
- AST results should not be used for continuous glucose monitor calibration or for use in insulin dose calculations
- Single-patient use only system; should not be shared

The FOCUS PRO Blood Glucose Monitoring System

- For Prescription Use
- Not for neonatal use
- Not for screening or diagnosis of diabetes mellitus
- This system has not been validated in the critically ill
- Alternative site testing (AST) can be used only during steady-state blood glucose conditions
- AST results should not be used for continuous glucose monitor calibration or for use in the insulin dose calculations
- This system should only be used with single-use, auto-disabling lancing devices

4. Special instrument requirements:

FOCUS Blood Glucose Meter  
FOCUS Pro Blood Glucose Meter

**I. Device Description:**

This is a modification of a previously cleared device to include housing/material construction changes and software modification to include optional ketone test alert and auto control detection.

The FOCUS Blood Glucose Monitoring System consists of the FOCUS Blood Glucose meter (sold separately), 10 FOCUS Test Strips (sold separately), FOCUS Control Solution Level 1 (sold separately), Lancing Device for single patient use only and lancets, clear cap (sold separately), log book for recording test results carry case, and User Manual.

The FOCUS PRO Blood Glucose Monitoring System consists of the FOCUS PRO Blood Glucose meter (sold separately), 10 PRO FOCUS Test Strips (sold separately), FOCUS Control Solution Level 1 (sold separately), and User Manual.

Each test strip contains the following reagent compositions: flavin adenine dinucleotide-glucose dehydrogenase (FAD-GDH from *Aspergillus Oryzae*); mediator ; and other non-reactive ingredients.

Control Solution level 1 is included in the kits, and control solution levels 2 and 3 are sold

separately. Each level control solution vial contains 3.0 ml aqueous solution.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
Nova One Blood Glucose Monitoring System
2. Predicate 510(k) number(s):  
k122435
5. Comparison with predicate:

Item	Candidate device FOCUS Blood Glucose Monitoring System (Self- Monitoring)	NOVA One Blood Glucose Monitoring System (Predicate Device, k122435)
<b>Similarities</b>		
Indication For Use	It is intended to be used for quantitative measurement of glucose in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same
Assay Method	Colorimetric Electrochemical Sensor	Same
Test Range	20 – 600 mg/dL	Same
Sample volume	0.40µl	same
Test time	4 seconds	same
Sample type	Glucose in venous and arterial whole blood and in fresh capillary whole blood obtained from the fingertip or forearm.	same
Hematocrit	25% to 60%	Same
Coding	None	Same
<b>Differences</b>		
Ketone Alert	Yes, when glucose value is above 240 mg/dL. Feature can be turned on/off by the user during set up.	N/A
Automatic Control Detection	Yes, identifies control sample as a control.	N/A

Item	Candidate Device FOCUS PRO Blood Glucose Monitoring System (Professional Monitoring)	NOVA One Blood Glucose Monitoring System (Professional Monitoring) (Predicate Device, k122435)
<b>Similarities</b>		
Indication For Use	<u>It is intended to be used for the quantitative measurement of glucose in venous, arterial and fresh capillary whole blood from the finger and forearm as an aid to monitor the effectiveness of diabetes control program.</u>	Same
Assay Method	Colorimetric Electrochemical Sensor	Same
Test Range	20 – 600 mg/dL	Same
Sample volume	0.40µl	same
Test time	4 seconds	same
Sample type	Glucose in venous and arterial whole blood and in fresh capillary whole blood obtained from the fingertip or forearm.	same
Hematocrit	25% to 60%	Same
Coding	None	Same
<b>Differences</b>		
Ketone Alert	Yes, when glucose value is above 240 mg/dL. Feature can be turned on/off by the user during set up.	N/A
Automatic Control Detection	Yes, identifies control sample as a control.	N/A

Item	Candidate device FOCUS Control Solutions	NOVA One Glucose Control Solutions (Predicate Device, k122435)
<b>Similarities</b>		
Indication For Use	It is intended to be used for use as a quality control check to verify that the meter and test strip are working together properly, and that the test is performing correctly.	Same
Levels	1,2, and 3	same
Matrix	aqueous	same

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

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

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

IEC 61010-1: Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General Requirements.

IEC 61010-2-101: Safety requirements for electrical equipment for measurement, control and laboratory use – Particular requirements for In Vitro Diagnostic (IVD) Medical Equipment.

**L. Test Principle:**

The FOCUS Blood Glucose Monitor and FOCUS PRO Blood 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):**

This submission is seeking clearance for modifications to a previously cleared device to include an optional ketone test alert and auto control detection. The sponsor uses the same analytical claim for the current test system and refers to the predicate 510(k) for the respective studies. No new performance studies were necessary for this device modification. The two systems in the submission only differ in their intended use (single-use vs. multiple-patient use) and the name; therefore, the performance data applies to both systems.

1. Analytical performance:

a. Precision/Reproducibility:

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.

Stability

**Glucose test strip:**

The candidate blood glucose test strips were previously cleared in k112638. However the brand name of the glucose strip has been updated to FOCUS Test Strips and FOCUS Pro Test Strips. The stability claims are 24 months when stored between temperatures of 15 to 30 °C between 10- 90% relative humidity and open-vial stability of 90 days when strips are stored at 15 to 30 °C between 10- 90% relative humidity as determined in k112638.

**Control Solution:**

The control solutions were previously cleared and stability and value assignment was previously established in k112638. The only difference is that they have been renamed to FOCUS Control Solutions (Levels 1, 2, 3).

*d. Detection limit:*

The reportable range is 20-600 mg/dL based on linearity study referenced in Section M.1.b. above.

*e. Analytical specificity:*

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 does 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 YSI:*

The system accuracy on finger stick and forearm samples was evaluated in k112638.

The system accuracy on venous and arterial samples was evaluated in k122435.

*b. Matrix comparison:*

Established in k122435.

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 finger and forearm study was evaluated in 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.

American Diabetes Association, Diagnosis and Classification of Diabetes Mellitus. Diabetes Care, Volume 36, Supplement 1, January 2013.

**N. Instrument Name:**

FOCUS Blood Glucose Meter  
FOCUS PRO Blood Glucose 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 \_\_\_\_\_ or No  \_\_\_\_\_

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

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

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes  \_\_\_\_\_ 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. Controls samples are identified as controls.

4. Specimen Sampling and Handling:

FOCUS Blood Glucose Monitor is intended to be used with capillary whole blood from the fingertip, which is directly applied to the test strip.

FOCUS PRO Blood Glucose Monitor 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:

The meter is a non-coding meter, therefore no coding is required by the user.

6. Quality Control:

The sponsor has three levels of control solutions (level 1 control solution is included with the kits). 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. Auto Control Detection automatically detects control solution when used in testing. The ionic strength of the control solution provides a current flow unique to just control solution. 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:**

1. Infection control

Infection Control Studies: The device systems are intended for single-patient use (FOCUS Blood Glucose Monitoring System) or multiple-patient use (FOCUS Pro Blood Glucose Monitoring System). Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, PDI Super Sani-Cloth Wipes (EPA Registration # 9480-4). Robustness studies were performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 10,950 cleanings and 10,950 disinfection steps with the 10,950 wipes. The robustness studies were designed to simulate 3 years of use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

2. Temperature and humidity operating conditions

The sponsor claims operating temperature from 57° F-104° F (14-40° C) and relative humidity range from 10% to 93%, as established in k112638.

3. EMC testing

EMC testing was evaluated and certified by The Compliance Management Group. A test certificate was issued to Nova on January 30, 2013.

4. 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.

5. Hematocrit study

The sponsor claims a hematocrit range of 25 to 60% as established in k112638.

6. Usability Study

The sponsor performed a Usability Study using 101 subjects to evaluate the FOCUS blood glucose monitoring system with respect to ergonomics, ease-of-use, and instructions for use.

7. Readability Evaluation of FOCUS Instructions

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.

8. Glucose Control Auto Detection Study

The sponsor performed a Glucose Control Auto Detection Study to verify the FOCUS blood glucose monitoring system correctly performs automatic glucose control detection

by identifying glucose control samples as a control. The sponsor evaluated three levels of glucose control solutions and 6 levels of venous whole blood (n=360) using three lots of test strips and six FOCUS/FOCUS PRO meters and correctly identified 100% of the control solutions.

9. Ketone Test Alert Study

The Ketone Test Alert (optional) is intended to alert users when blood glucose results are greater than 240 mg/dL so that users may check their ketone levels using an alternate method if it is part of their treatment plan. The sponsor performed a Ketone Test Alert Study to verify the FOCUS blood glucose monitoring system correctly performs the Ketone Test Alert on samples > 240 mg/dL.

10. Sample Volume Study

The sponsor claims that a minimum of 0.40µl of sample volume are required for this system, 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.