

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

A. 510(k) Number:

k070255

B. Purpose for Submission:

Clearance of the Nova Max Blood Glucose Monitoring System. This system is the same system that was cleared previously as the Becton Dickinson (BD) Logic and BD Paradigm Link systems. This premarket notification references the technical information contained in k041478. An additional claim for use of a single calibration code for all lots of test strips has been added.

C. Measurand:

Glucose

D. Type of Test:

Quantitative, glucose oxidase amperometric technology

E. Applicant:

Nova Biomedical Corporation

F. Proprietary and Established Names:

Nova Max™ Blood Glucose Monitor

Nova Max™ Glucose Test Strips

Nova Max™ Glucose Control Solutions (Normal, Low, High)

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 and Class I, reserved respectively.

3. Product code:

NBW, CGA, JJX

4. Panel:

Chemistry, 75

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Nova Max Blood Glucose Monitor is intended to be used for the quantitative measurement of glucose in 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. The Nova Max Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in capillary whole blood samples obtained from the fingertip, palm and forearm.

Nova Max Glucose Test Strips are intended for use only with the Nova Max Blood Glucose Monitor and the BD Logic® and Paradigm Link® Blood Glucose Monitors for quantitative tests. The Nova Max Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in capillary whole blood samples obtained from the fingertip, palm and forearm. The Glucose Monitor is calibrated to provide plasma equivalent results to laboratory methods. Nova Max Glucose Test Strips are for testing outside the body (in vitro diagnostic use only).

Nova Max Control Solutions are intended for use with the Nova Max Blood Glucose Monitor, BD Logic® and Paradigm Link® Blood Glucose Monitors 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).

3. Special conditions for use statement(s):

The device is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

4. Special instrument requirements:

The test strips and controls are for use with Nova Max, BD Logic, or BD Paradigm Link glucose monitors.

I. Device Description:

The Nova Max Blood Glucose Monitoring System consists of the Nova Max Blood Glucose Monitor, Nova Max Blood Glucose Test Strips, and Nova Max Control Solutions (Normal, Low, High). The Nova Max Control Solution, Normal, is provided with the test kit while the Low and High Control Solutions must be purchased separately.

When Nova Max Blood Glucose Test Strips are used in conjunction with the Nova Max Blood Glucose Monitor, calibration coding is not required. When Nova Max Blood Glucose Test Strips are used with either the BD Logic or BD Paradigm Link glucose monitors, users are instructed to use “Code 20” for all test strip lots.

J. Substantial Equivalence Information:

1. Predicate device name(s):

BD Logic Blood Glucose Monitoring System

2. Predicate 510(k) number(s):
k022581, k041478
3. Comparison with predicate:

Similarities and Differences

Characteristic	Proposed Nova Max Blood Glucose Monitor System	Predicate BD Logic Blood Glucose Monitor K022581, K041478
Measuring Range	Same as Predicate	20-600 mg/dL
Operating Principle	Same as Predicate	Glucose oxidase biosensor
Intended Use	Same as Predicate: 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 and by healthcare professionals in clinical settings as an aid to monitor the effectiveness of diabetes control. The Nova Max Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip, forearm and palm.	The BD Logic 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 BD Logic Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip, forearm and palm.
Sample type	Same as Predicate	Capillary blood: fingertip, forearm, palm
Sample size	Same as Predicate	0.3 uL
Glucose Units	mg/dL	mg/dL; mmol/L
Sample application	Same as Predicate	Test strip capillary draw
Handheld meter?	Yes	Yes
Data storage	Up to 250 blood glucose and control solution tests	Up to 250 blood glucose and control solution tests, Up to 250 Insulin Records
Analysis Time	5 sec	5 sec
Weight	Same as Predicate.	2.65 oz.
Insulin Tracking feature	No	Yes
Power source	Same as Predicate	3 volt coin cell battery
Accessories to the Monitor:		
Controls:	Same as Predicate	Liquid, 3 levels
Test Strips : Active reagent:	Same as Predicate	Glucose Oxidase
Test Strip	No User Input required for Nova Max;	User Input Required for each lot of

Calibration Coding	User Input required for BD Logic and Paradigm Link – one code for all strip lots.	Strips
---------------------------	---	--------

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

- Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline- Second Edition (CLSI EP5-A2)
- Interference Testing in Clinical Chemistry; Approved Guideline (CLSI EP7-P)
- Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline Second Edition (CLSI EP9-A2)
- Evaluation of Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (CLSI EP6-A)
- In Vitro-diagnostic test systems-Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (ISO 15197, 2003)
- IEC 61010-1:2001
- IEC 61010-2101: 2002

L. Test Principle:

To perform a test, the test strip is first inserted into the monitor. A drop of blood is applied to the end of the strip and drawn into the reaction space via capillary action. Glucose in the sample reacts with glucose oxidase and ferricyanide, generating a current that is proportional to the glucose concentration in the sample. The test result is displayed on the monitor in 5 seconds.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

See premarket notification k041478

b. *Linearity/assay reportable range:*

See premarket notification k041478

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

The Nova Max Test Strips are manufactured to meet a single calibration code requirement so that all test strips vials will have the same calibration code. The sponsor has established processes to ensure that the Nova Max Test Strip performance can support use of a single calibration code. The test strip manufacturing lot release acceptance criteria include specifications for accuracy, quality control recovery, and imprecision. The sponsor also provided a risk analysis that addresses issues related to the test strip manufacturing.

The requirement for a user inputted calibration code for each lot of strips is no longer necessary when using the Nova Max Blood Glucose Monitor. When Nova Max Blood Glucose Test Strips are used with either the BD Logic or BD Paradigm Link glucose

monitors, users are instructed to use “Code 20” for all test strip lots.

d. Detection limit:

See premarket notification k041478

e. Analytical specificity:

See premarket notification k041478

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

See premarket notification k041478

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):

See premarket notification k041478

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

See premarket notification k041478

N. Instrument Name:

Nova Max™ Blood Glucose Monitor

O. System Descriptions:

1. Modes of Operation:

Each Nova Max test strip should only be used once and discarded. Nova Max test strips may be used with the Nova Max, BD Logic, and BD Paradigm glucose meters.

2. Software:

FDA reviewed the Hazard Analysis and software development processes for this line of product types in k022581 and k041478 and updated functions in this submission.

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, the palm, or the forearm only. When blood glucose levels are changing rapidly, only fingertip or palm testing should be performed. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

The requirement for a user inputted calibration code for each lot of strips is not necessary when using the Nova Max Blood Glucose Monitor. When Nova Max Blood Glucose Test Strips are used with either the BD Logic or BD Paradigm Link glucose monitors, users are instructed to use “Code 20” for all test strip lots.

6. Quality Control:

The sponsor provides the Nova Max™ Glucose Control Solution, Normal with the test system. Nova Max™ Glucose Control Solutions, Low and High may be purchased separately. The acceptable range for each control level is printed on the test strip vial label and box. The user is directed to repeat the test with a new test strip if the control results fall outside these ranges. If the problem continues, the user should call customer service at the phone number provided.

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

None.

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.