510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k101633

B. Purpose for Submission:

New device

C. Measurand:

Quality control materials for Blood Glucose and β-Ketone Monitoring Systems

D. Type of Test:

Quality Control Materials

E. Applicant:

Nova Biomedical Corporation

F. Proprietary and Established Names:

Nova Max Plus Glucose and β-Ketone Control Solutions

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJY	Class I, reserved	21 CFR 862.1660 Quality Control Material	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   Refer to indication for use below

2. Indication(s) for use:

   The Nova Max Plus Glucose and β-Ketone Control Solutions are intended for use with the Nova Max Family of Monitors (Nova Max, Nova Max Plus, and Nova Max Link), BD Logic and Paradigm Link Monitors, Nova Max Glucose Test Strips, and Nova Max Plus Ketone Test Strips as a quality control check to verify the accuracy of blood Glucose

and β-Ketone test results.

3. Special conditions for use statement(s):

   For *in vitro* diagnostic use only

   For over the counter use

4. Special instrument requirements:

   Nova Max Family of Monitors (Nova Max, Nova Max Plus, and Nova Max Link), BD Logic and Paradigm Link Monitors, Nova Max Glucose Test Strips, and Nova Max Plus Ketone Test Strips.

I. Device Description:

The control solutions are aqueous assayed solutions containing Glucose and β-Ketone. There are two levels of controls (Level Mid and Level High).

The non-reactive formulation ingredients include: preservative, dye, and viscosity-adjusting agent.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Nova Max Plus Blood Glucose Control Solutions and Nova Max Plus Ketone Control Solutions

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

   k091547

3. Comparison with predicate:

Items	Nova Max Plus Glucose and β-Ketone Control Solutions (Candidate Device)	Nova Max Plus Glucose and β-Ketone Control Solutions (Predicate Device k091547)
Intended Use	The Nova Max Plus Glucose and β-Ketone Control Solutions are intended for use with the Nova Max Family of Monitors (Nova Max, Nova Max Plus, and Nova Max Link), BD Logic and BD Paradigm Link Monitors, Nova Max Glucose Test Strips, and Nova Max Plus Ketone Test Strips as a quality control check to verify the	Same

	accuracy of blood Glucose and β-Ketone test results.	
Analyte(s)	Glucose and β-Ketone	Same
Levels of Controls	2	3
Target Concentration	Glucose: 106 mg/dL (Level Mid) 285 mg/dL (Level High)	Glucose: 62 mg/dL (Level Low) 121 mg/dL (Level Normal) 320 mg/dL (Level High)
	β-Ketone: 1.1 mM (Level Mid) 2.6 mM (Level High)	β-Ketone: 1.2 mM (Level 1) 2.9 mM (Level 2) 5.2 mM (Level 3)
Matrix	Preservative, dye, and viscosity-adjusting agent	Same

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

None referenced

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable

b. Linearity/assay reportable range:

Not applicable

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

Traceability

- Glucose controls are traceable to NIST (National Institute of Standards and Technology) D-Glucose SRM 917B.

- Nova Max Plus Ketone controls are traceable to an in house standard prepared gravimetrically from commercially available materials. No Standard Reference Material (SRM) is currently available for B-Hydroxybutyrate.

Value Assignment:

- Glucose:

  The target values are 106 mg/dL (Level Mid) and 285 mg/dL (Level High). The lot specific range was assigned as mean ± 17%. The Mean and SD was calculated from 150 test results (2 tests per strip lot per monitor per day, using 3 strip lots and 5 monitors over 5 days of testing).

- Ketone:

  The target values are 1.1 mM (Level Mid) and 2.6 mM (Level High). The lot specific range was assigned as mean ± 20% for the high control, and mean ± 0.2 mM for the mid control. The Mean and SD was calculated from 150 test results (2 tests per strip lot per monitor per day, using 3 strip lots and 5 monitors over 5 days of testing).

Stability:

- Shelf life stability:

  Real-time testing at room temperature (25^{o}C) and accelerated testing at 40^{o}C and 50^{o}C were conducted. The stability study protocol and the acceptance criteria have been reviewed and found to be acceptable. The predicted shelf-life, based on results of accelerated testing, is 2.5 years at room temperature (25^{o}C). Real-time stability testing is on-going to support the claimed shelf life of 24 months at room temperature (25^{o}C).

- Open-Vial Stability:

  The stability study protocol to determine open-vial stability of the controls and the acceptance criteria have been reviewed and found to be acceptable. The Nova Max Plus Glucose and β-Ketone Control Solutions are stable after opening for at least 90 days at room temperature (25^{o}C).

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

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:

Expected values are provided on the vial labels.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.