

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

K041016

B. Purpose of the Submission:

This is a new product.

C. Analyte:

Glucose

D. Type of Test:

Quality Control Material

E. Applicant:

Nova Biomedical

F. Proprietary and Established Names:

Nova Glucose Low/High Level Control Solutions

G. Regulatory Information:

1. Regulation section:
CFR 21 862.1660
Single Analyte Control (Assayed and Unassayed)
2. Classification:
I, Reserved
3. Product Code:
JJX
4. Panel:
Chemistry (75)

H. Intended Use:

1. Intended use(s):
Refer to Indications for use.
2. Indication(s) for use:
The Nova Glucose Low/High Level Control Solutions are assayed quality control materials, which are used to verify the performance of BD Logic Blood Glucose Monitoring System, BD Latitude Diabetes Management System, BC/MiniMed Blood Glucose Monitor, and MiniMed Paradigm Link Blood Glucose Monitor. This control is an OTC product intended for use in the home setting.

The product is for in vitro diagnostic use.
The device is for over-the-counter use.

3. Special condition for use statement(s):
None

4. Special instrument Requirements:
The instruments appropriate for monitoring with this material are listed in the Indications for Use statement.

I. Device Description:

The solutions are two levels (Low and High) aqueous assayed solutions, containing D-glucose, blue dye, and preservative, that is adjusted to have a viscosity to simulate the reaction of whole human blood when used with glucose monitoring systems. They contain no products of human origin.

The targeted concentrations for the solutions are 60 and 300 mg/dL of glucose.

Although being cleared together, and using the same package insert, the sponsor indicates the products will be packaged and sold separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Nova Glucose NORMAL Control
2. Predicate K number(s):
K033433
3. Comparison with predicate:
Both devices are made by the same company, and have the same intended use. They are very similar in make up, except that the new product has a dye added to it (according to the sponsor via telephone on 4/28), and the concentrations of glucose added to each solution vary. The new product is also expanding the claim to include use of the Medtronic MiniMed Blood Glucose Monitoring systems.

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

The sponsor did not reference any standards in their submission.

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 (controls, calibrators, or method):*

The product consists of two levels of control material, which are traceable to NIST Glucose SRM 917B.

Stability studies are summarized. The sponsor specifies the frequency of testing, the method for testing the materials, environmental conditions of storage, and acceptance criteria for the study (within 5% recovery from baseline at day one). Accelerated studies are being used by the sponsor to estimate the expiration date, however, on-going real time studies are being performed. All procedures appear to be standard for the industry.

The sponsor has presented precision studies involving the materials, i.e., less than 5% CV for both levels. They have also indicated studies to demonstrate that no observable microbial or mold colonies were observed in 2 lots of their product.

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):*

4. Clinical cut-off:
Not applicable.
5. Expected values/Reference range:
Not applicable.

N. Conclusion:

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