

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

A. 510(k) Number:

K032819

B. Analyte:

Glucose

C. Type of Test:

N/A

D. Applicant:

Bionostics, Inc.

E. Proprietary and Established Names:

Glucose Control Soutlion for CHdiagnostics SeNova Blood Glucose Monitoring System

F. Regulatory Information:

1. Regulation section:
21 CFR 862.1660
2. Classification:
Class I
3. Product Code:
JJX
4. Panel:
CH

G. Intended Use:

1. Indication(s) for use:
Glucose Control Solution for CHdiagnostics SeNova Blood Glucose Monitoring System is intended for use to verify the performance of the CHdiagnostics SeNova BGM System at glucose levels within the reportable range. The Glucose Control Solution is intended for use by healthcare professionals and people with diabetes mellitus at home.
2. Special condition for use statement(s):
N/A
3. Special instrument Requirements:
For use with the CHdiagnostics SeNOva Blood Glucose Monitoring System

H. Device Description:

The Glucose Control Solution for CHdiagnostics SeNova Blood Glucose Monitoring System is a three level (low, normal and high), viscosity adjusted, aqueous liquid glucose control solution. The product is packaged in plastic bottles with dropper tips for application of the solution to test strips. The control has a blue color to help users see the solution while dispensing onto a test strip. The target values are 55, 140, and 330 mg/dL.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Bionostics Multi-Meter Glucose Calibration Verification Material
2. Predicate K number(s):
K012430
3. Comparison with predicate:
Both devices are buffered, aqueous solutions of D-glucose that are manufactured using the same processes. They differ in that the predicate device has 5 levels and the subject device has three levels.

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

N/A

K. Test Principle:

N/A

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
N/A
 - b. *Linearity/assay reportable range:*
N/A
 - c. *Traceability (controls, calibrators, or method):*
N/A
 - d. *Detection limit:*
N/A
 - e. *Analytical specificity:*
N/A
 - f. *Assay cut-off:*
N/A
2. Comparison studies:
 - a. *Method comparison with predicate device:*
N/A
 - b. *Matrix comparison:*
N/A
3. Clinical studies:
 - a. *Clinical sensitivity:*
N/A

b. Clinical specificity:

N/A

c. Other clinical supportive data (when a and b are not applicable):

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

N/A

M. Conclusion:

Based upon the information provided, I recommend that the Bionostics Glucose Control Solution for CHdiagnostics SeNova Blood Glucose Monitoring System be found substantially equivalent to predicate devices according to 21 CFR 1660.