

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

A. 510(k) Number:

k051514

B. Purpose for Submission:

Modification of existing device.

C. Measurand:

Glucose, home glucose monitoring test

D. Type of Test:

Quantitative

E. Applicant:

Hypoguard USA, Inc.

F. Proprietary and Established Names:

Assure Pro Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1345, Glucose Test System

2. Classification:

Class II

3. Product code:

NBW, system, test, blood glucose, over the counter

CGA, glucose oxidase, glucose

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

The Assure Pro Blood Glucose Monitoring System is intended to measure glucose quantitatively in blood and other bodily fluids.

2. Indication(s) for use:

Assure Pro Blood Glucose Monitoring System:

The Assure Pro Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (In Vitro Diagnostic Use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Assure Pro Glucose Meter:

The Assure Pro Blood Glucose Meter is intended for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (In Vitro Diagnostic Use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Assure Pro Blood Glucose Test Strips:

Assure Pro Test Strips are intended for the quantitative measurement of glucose in

fresh capillary whole blood when used with the Assure Pro Blood Glucose Meter. Testing is done outside the body (In Vitro Diagnostic Use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Assure Pro Control Solution:

For use with Assure Pro Blood Glucose and Assure Pro Test Strips as a quality control check to verify the accuracy of blood glucose test results.

3. Special conditions for use statement(s):

For fingerstick use only.

This product is intended for over-the-counter and point-of-care use.

4. Special instrument requirements:

Assure Pro Glucose Meter

I. Device Description:

The Advance Micro-Draw Blood Glucose Monitoring System consists of a hand-held blood glucose meter, test strips, and control materials. Each lot of test strips has a code chip containing lot-specific calibration information that the machine reads automatically. The meter is turned on by strip insertion; the user then supplies finger-tip blood or control solution to the strip and the meter starts the assay, which completes in 15 seconds. The meter's software converts the results read off the test strip into a plasma glucose concentration and displays the value on the meter's LCD screen.

J. Substantial Equivalence Information:

This submission covers modifications to the glucose meter. The original meter and the control materials were previously cleared under k020232 as the Hypoguard Advance. A strip modification was cleared under k031388. An alternate site claim was added under k041881 but alternate site testing is not claimed in this submission.

1. Predicate device name(s):

Hypoguard Advance Micro-Draw

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

k020232, k031388, k041881

3. Comparison with predicate:

Certain features of the glucose meter have been modified from the predicate:

- the test strip port is now on the top of the meter
- a strip-ejection mechanism has been added
- an adjustable backlight feature has been added
- alarm features have been added

The indications for use, the calculation algorithm, the test strips, and the control solutions are unchanged.

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

Precision studies were performed in accordance with CLSI EP5-A.

L. Test Principle:

The test is based on the release of electrical potential after a two-step reaction where glucose and ferricyanide, in the presence of glucose oxidase, are converted into gluconolactone and ferrocyanide. Ferrocyanide, when electrical current is applied, becomes ferricyanide and releases electrons; the increase in current measured by the meter is proportional to the glucose concentration.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision was tested in the manufacturer's facility based on CLSI EP5-A. Whole blood samples from non-diabetic volunteers were spiked to yield 6 glucose concentrations ranging from 30 – 600 mg/dL. The lowest level of blood was allowed to glycolyze; all other samples were tested within four hours of collection. Results were compared to YSI values. One strip lot was tested. Within-run precision was tested on twenty replicates of each glucose level; between-day precision was tested by six independent runs of within-day precision. The sponsor set acceptance criteria as total CV% not to exceed 9.5 %. Testing results are summarized in the table below:

Summary of Precision Testing: Hypoguard Assure Pro

	Target Range (mg/dL)						Avg
	30-50	51-110	111-150	151-250	251-400	500-600	
Within Run CV (%)	5.7	4.7	5.5	4.6	5.1	4.8	5.1
Between Run CV (%)	18	7.4	4.7	6	7	4.8	8
Total CV (%)	18.8	7.8	5.2	6.5	8.1	7.1	8.9

b. *Linearity/assay reportable range:*

The data from the precision study was used to determine linearity by plotting the average YSI value against the average meter value for each glucose level for each of the six days of testing. The regression analysis showed a linear relationship between the Assure Pro and the YSI method: $y = 0.92x + 23.5$, $R = 0.98$.

The sponsor conducted another linearity study using seven levels of glucose-spiked blood covering the same range as the previous testing; two different test strip lots were tested on three Assure Pro meters ($n = 12$ per level). The regression analysis showed a linear relationship between the Assure Pro and the YSI method: $y = 0.96x + 6.6$, $R = 0.99$.

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

These parameters were established in the original submission (k020232).

d. *Detection limit:*

The low and high detection limits for the Assure Pro system have been set at 20 and 600 mg/dL glucose. Twenty blood samples < 20 mg/dL (by YSI) and 20 samples between 800-900 mg/dL generated the expected “LO” and “HI” result respectively.

e. Analytical specificity:

These parameters were established in the original submission (k020232).

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

See Clinical Studies section below.

b. Matrix comparison:

Not applicable. The meter’s software adjusts the whole-blood glucose reading to a plasma-equivalent reading.

3. Clinical studies:

One hundred diabetics participated in a study to establish the clinical characteristics of the Assure Pro System. Testing included men and women, both Type 1 and Type 2 diabetics, who span a wide range of education, and spanned an age range from 18 to 81. Each participant was given the product labeling, asked to read it, and then perform the test without the help of the clinical study staff. The clinical staff collected capillary blood for YSI testing and obtained results on two Assure Pro meters and the predicate meter. Ten additional people with blood glucose levels below 100 mg/dL were tested at the sponsor’s facility; some of these were not diabetics.

a. Clinical Sensitivity:

The relationship between the glucose value obtained from YSI testing and the average of the finger-stick values is described below:

Comparison of Assure Pro Glucose Values in Clinical Studies

	Regression Analysis	r value
Participant vs. YSI	$y = 0.89x + 15.6$	0.94
Professional vs. YSI	$y = 0.91x + 12.0$	0.96
Professional vs. Predicate	$y = 0.94x + 9.7$	0.97

One method of comparing the significance of variability between finger-stick values and YSI values is to determine how close the values are to each other. Bias describes the difference as a percent of the finger-stick value. The more tests that have a low percent bias suggests that the two tests give similar readings:

Assure Pro Percent Bias in Clinical Study

% Bias Range	% Values in Range	
	Participant (n=110)	Professional (n=220)
≤ 10 %	60	68
11 – 20%	31	26
> 20 %	9	6

However, differences between the two measurement systems may or may not affect clinical decisions; the Clarke Error Grid method was used to determine if differences between the methods might affect clinical outcome.

Clarke Error Grid Analysis for the Assure Pro Clinical Study

Tester	% of Results in Clarke Error Grid Zone				
	A	B	C	D	E
Participant	90%	10%	0	0	0
Professional	94%	5%	0	1%*	0
Significance of Error	Clinically Accurate Treatment	Benign or No Treatment Change	Over-Correcting Treatment	Failure to Detect and Treat	Erroneous Treatment

* YSI value = 63 mg/dL, Assure Pro value = 78 mg/dL. The cut-off for the D-zone at 63 mg/dL is a meter value of 76 mg/dL or higher.

- 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:
The normal fasting adult glucose range for a non-diabetic is 70 – 105 mg/dL. One to two hours after a meal, normal blood glucose levels should be less than 140 mg/dL. A medical professional should determine the range that is appropriate for diabetes patients.

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.

