

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

A. 510(k) Number:

k041881

B. Purpose for Submission:

Previously cleared product with new indications for use (alternate site testing)

C. Analyte:

Glucose, home glucose monitoring kit

D. Type of Test:

Quantitative electrochemical assay

E. Applicant:

Hypoguard USA Inc.

F. Proprietary and Established Names:

Advance Micro-Draw Glucose Monitoring System

Advance Micro-Draw Test Strip

Advance Micro-Draw High Control Solution

Advance Micro-Draw Normal Control Solution

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1345, Blood Glucose Test System, Over-the-Counter

21 CFR §862.1660, Single (specified) analyte controls (assayed/unassayed)

2. Classification:

Class II

3. Product Code:

NBW, CGA Glucose Test System

JJX Quality Control Material

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

Advance Micro-draw™ Blood Glucose Monitoring System:

The Advance Micro-draw™ Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood

samples drawn from the fingertips or palm. 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.

Advance Micro-draw™ Blood Glucose Test Strips:

Advance Micro-draw™ Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips or palm. Advance Micro-draw™ Test Strips must be used with the Advance Micro-draw™ Blood Glucose Meter. Testing is done outside the body (*In Vitro* diagnostic use). They are 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.

Advance Micro-draw™ Control Solution:

For use with Advance Micro-draw™ Blood Glucose Meter and Advance Micro-draw™ Test Strips as a quality control check to verify the accuracy of blood glucose test results.

3. Special condition for use statement(s):
This product is intended for over-the-counter and point-of-care use.
4. Special instrument requirements:
None; this is a complete blood glucose monitoring system.

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 fingertip 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 meter and the control materials were previously cleared under k020232 as the Hypogaurd Advance. A strip modification was cleared under k031388.

1. Predicate device name(s):
LifeScan OneTouch Ultra Blood Glucose Monitoring System
2. Predicate K number(s):
k024194

3. Comparison with predicate:

Similarities		
Item	Advance MicroDraw	OneTouch Ultra
Intended Use	Blood glucose monitoring for home and point-of-care	Same
System Components	Meter, calibration code strip, test strip, check strip, battery, control solutions	Same
Blood Sampling Sites	Fingertip (capillary) Palm	Fingertip (capillary) Arm
Test Principle/ Enzyme/ Mediator	Electrochemical/ Glucose oxidase/ Potassium ferricyanide	Same/ same/ same
Calibration	Automatic (coding chip)	Same
Stability	Strips and controls, 3 mo after opening	Same
Power Source	3V lithium battery	Same
Hematocrit Range	30 – 55%	Same
Measurement Range	20 to 600 mg/dL	Same
Differences		
Item	Advance MicroDraw	OneTouch Ultra
Test Range	30 – 550 mg/dL	20 – 600 mg/dL
Sample Volume	1.5 ul	1.0 ul
Test Time	15 seconds	5 seconds
Operating Range	59 – 86° F, relative humidity < 80%	43 – 111° F, relative humidity <90%
Memory Capability	250 test results	150 test results
Size	3.5” x 3” x 0.8”	3.1” x 2.2” x .85”
Weight	1.4 ounces	1.5 ounces

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

The sponsor did not reference any standards or guidance in this submission.

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:*

Established in the original submission (k020232)

b. Linearity/assay reportable range:

Established in the original submission (k020232)

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

Established in the original submission (k020232)

d. Detection limit:

Established in the original submission (k020232)

e. Analytical specificity:

Established in the original submission (k020232)

f. Assay cut-off:

Not applicable

2. Comparison studies:

The comparison study in this submission was intended to support an alternate site testing claim for the fleshy areas of the palm by comparing blood glucose values obtained from the palm to blood glucose values obtained from the fingertip.

Participants with diabetes (n=101) ranged in age, education, and years of diabetes; subjects were about equally divided between males and females, and type-2 diabetes was more common in the participant groups. All participants had hematocrits within the stated range of the meter. The majority, 78/101 (77%) of the participants had fingertip blood glucose readings between 71 – 240 mg/dL while 19/101 (19%) of the participants had fingertip blood glucose readings over 240 mg/dL. Only 4/101 (4%) of the participants were hypoglycemic (<70 mg/dL) during the test; one of these participants had rapidly changing blood glucose during the testing (i.e. was ‘non-steady state’). This participant was the only subject that was not in steady-state during the testing.

Each participant was given the product labeling, asked to read it, and then perform the test. Sometimes the palm was tested first (by the participant and a health care worker in that order), other times the finger-stick was performed by the professional first. One test was performed by each person. Another finger-stick reading was collected at the very end of all the tests (so there were always two finger-stick values).

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

Comparison of Advance Micro-draw Palm Glucose Values to Finger-stick Values in Clinical Studies

	Regression Analysis	r value
Participant vs. Finger-stick	$y = 1.02x + 5.0$	0.98
Professional vs. Finger-stick	$y = 0.99x + 5.7$	0.98

One method of comparing the significance of variability between finger-stick values and palm-stick 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 average bias for palm was 5.1% for participants and 2.8% for professionals.

The more paired tests that have a low percent bias suggest that the two test sites give similar readings.

Percent Bias of Palm-Stick Values; Advance Micro-draw

% Bias Range	% Values in Range	
	Participant	Professional
≤10%	72	76
11-20%	15	21
>20%	13	3

The Clarke Error Grid method was used to determine if differences between the methods might affect clinical outcome. The results are shown in the table below:

Clarke Error Grid Analysis for Palm Testing: Advance Micro-draw

Site	n=	Tester	% of Results in Clarke Error Grid Zone				
			A	B	C	D	E
Palm	101	Participant	86%	13%	0	1%*	0
		Professional	96%	4%	0	0	0
		Significance of Error	Clinically Accurate Treatment	Benign or No Treatment Change	Over-Correcting Treatment	Failure to Detect and Treat	Erroneous Treatment

* During testing this subject was hypoglycemic and not in steady-state however professional testing of this subject fell into Zone A.

The sponsor did not perform studies that compare alternate site testing to fingertip testing during times when glucose is changing rapidly (non-steady state).

Therefore people using the meter should be careful to use alternate site testing only when glucose levels would not be expected to be changing rapidly: during fasting or more than two hours after a meal. Insulin levels would be expected to be changing rapidly just after eating, after insulin dosing, or exercise. If the

patient is experiencing symptoms of hypoglycemia it is important to use fingertip testing for the most accurate reading.

a. *Method comparison with predicate device:*

Not applicable. This submission compared the meter's finger-stick performance to palm-stick performance (see above).

b. *Matrix comparison:*

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

3. Clinical studies:

a. *Clinical sensitivity:*

See Comparison Studies above.

b. *Clinical specificity:*

See Comparison Studies above.

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.