

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

k063068

B. Purpose for Submission:

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

C. Measurand:

Glucose

D. Type of Test:

Quantitative, Glucose Oxidase electrochemical assay

E. Applicant:

Arkray, Inc.

F. Proprietary and Established Names:

Ferrara Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1345, Glucose test system

2. Classification:

Class II, test system

3. Product code:

CGA and NBW

4. Panel:

75, Clinical Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

Ferrara Blood Glucose Monitoring System:

The Ferrara Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary 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.

Ferrara Blood Glucose Test Strips:

Ferrara Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip or palm. Ferrara Test Strips must be used with the Ferrara Blood glucose Meter. Testing is done outside the body (In Vitro diagnostic use). They are intended 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.

Ferrara Control Solution:

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

3. Special conditions for use statement(s):

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

Fingertip testing only (not testing using capillary blood from the palm) should be performed in the following situations (i.e., when glucose levels are rapidly changing):

- Within 2 hours after a meal
- Within 2 hours after insulin dosing
- If a patient has a history of hypoglycemia, is experiencing symptoms of low blood sugar, or suffers from hypoglycemic unawareness
- As a confirmation of a palm glucose test result when it is inconsistent with how a patient feels

4. Special instrument requirements:

Ferrara Blood Glucose Meter

I. Device Description:

The Ferrara Blood Glucose Monitoring System consists of a 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, palm blood or control solution to the strip and the meter starts the assay, which completes in 10 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. The meter displays results in units of mg/dL only.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Hypoguard Advance Micro draw and Assure Pro

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

k041881 and k053079

3. Comparison with predicate:

Similarities and Differences			
Item	Device	Predicate 1	Predicate 2
		Advance (AST)	Assure Pro
Blood Source	Fingertip, palm	Fingertip, palm	Fingertip
Minimum Sample Volume	1.0 µL	1.5	1.0 µL
Strip Holder Location	Bottom of meter	Bottom of meter	Top of meter
Test Time (sec.)	10	15	10
Power Source	1 replaceable 3V Lithium CR2032	1 replaceable 3V Lithium CR2032	2 AAA batteries
Dimensions	3.2” x 2.6” x 0.6”	3.5” x 3” x 0.8”	4.1” x 2.4” x 1”
Weight	1.4 ounces	1.4 ounces	2.5 ounces
Button pattern	Memory in middle	Memory on right	Memory in middle
Units of measurement	Only mg/dl	mg/dL and mmol/L	Only mg/dL
# of meter buttons	3	identical	identical
Reference	Plasma	identical	identical
Sample Type	Capillary whole blood	identical	identical
Sample Application	Apply blood to test strip; end capillary fill	identical	identical

Similarities and Differences			
Item	Device	Predicate 1 Advance (AST)	Predicate 2 Assure Pro
Hematocrit Range	30-55%	identical	identical
Control Solution(s)	Two levels available	identical	identical
Operating T° Range	50°F to 104 °F	identical	identical
Operating Humidity Range	20% to 80%	identical	identical
Display	Liquid crystal	identical	identical
Results presentation	Liquid crystal display	identical	identical
Memory Capabilities	250 results	identical	identical
Test Start	Insert strip into meter	identical	identical
Calibration Curve	Automatic w/ keycode	identical	identical
Measurement Range	20 to 600 mg/dL	identical	identical

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

None Referenced

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 (k053079)

b. Linearity/assay reportable range:

Established in the original submission (k053079)

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

Established in the original submission (k053079)

d. Detection limit:

Established in the original submission (k053079)

e. Analytical specificity:

Established in the original submission (k053079)

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

3. Clinical studies:

The consumer study was performed at one POC site with a total of 106 lay-users. The lay-users ranged in age, education and were equally divided between males and females; and had either type-1 or type-2 diabetes. Each participant performed a self-test on their palm and tested their blood using the instructions in the User's guide. A trained professional then performed a palm test and fingerstick test, testing the blood on the same meter.

	Number of samples	Linear Regression	r value	Sample Range (mg/dL)	% Error Grid	
					A	B
Lay-user palm vs Professional finger stick	106	$y = 0.97x + 11.03$	0.97	45-328	90	9
Professional palm vs Professional finger stick	109	$y = 0.93x + 12$	0.98	45-328	95	3
Professional palm vs Professional finger stick with no exclusions*	110	$y = 0.89x + 16.83$	0.96	45-328	95	3

* During the professional testing there was one measurement that showed a difference between the palm (155 mg/dL) and the fingertip (281 mg/dL). This row represents the data with this sample included.

A Bias was calculated for the lay-user and professional palm against the professional fingertip results. The bias for the lay-user was 6.2% and the professional was 1.7%. Based on this information the sponsor included the following statement in the labeling:

On average, blood taken from the palm may give results as much as 5% higher than blood taken from the fingertip.

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 90 – 130 mg/dL. Two hours after a meal, normal blood glucose levels should be less than 180 mg/dL. A medical professional should determine the range that is appropriate for diabetes patients.

N. Instrument Name:

Ferrara Blood Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for additional readings.

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes X or No _____

3. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

This device is intended to be used with capillary whole blood from the fingertip and palm. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

Calibration is achieved by inserting a key code into the Coding Chip Port on the side of the meter. A new coding chip is provided with each container of strips.

6. Quality Control:

The sponsor is providing a high and low glucose control solution with this device. To mark the test result as a control the user is instructed to press and hold the Back or Forward button until a display of a control vial appears in the upper right corner on the display. This prevents control results from being stored in the internal memory. An acceptable range for each control level is printed on the test strip vial label. If control results fall outside these ranges, the user is referred to a list of troubleshooting steps and the customer care line.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:

None

Q. Proposed Labeling:

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

R. Conclusion:

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