

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

A. 510(k) Number:

K061991

B. Purpose for Submission:

New Device

C. Measurand:

Platelets

D. Type of Test:

Aggregation, qualitative

E. Applicant:

Helena Laboratories

F. Proprietary and Established Names:

Plateletworks Arachidonic Acid Kit

G. Regulatory Information:

1. Regulation section:

21 CFR 864.5700, Automated Platelet Aggregation System

2. Classification:

Class II

3. Product code:

GHR, Reagent, Platelet Aggregation

4. Panel:

81 (Hematology)

H. Intended Use:

1. Intended use(s):

Plateletworks Arachidonic Acid (PW-ACA) is an in vitro diagnostic screening test on whole blood for the qualitative determination of platelet inhibition by aspirin which inhibit arachidonic acid induced platelet aggregation. The change in platelet count due to activation and aggregation of functional platelets is measured using an electronic impedance-based cell counter.

2. Indication(s) for use:

Plateletworks Arachidonic Acid (PW-ACA) is an in vitro diagnostic screening test on whole blood for the qualitative determination of platelet inhibition by aspirin which inhibit arachidonic acid induced platelet aggregation. The change in platelet count due to activation and aggregation of functional platelets is measured using an electronic impedance-based cell counter.

3. Special conditions for use statement(s):

Not applicable.

4. Special instrument requirements:

Not applicable.

I. Device Description:

The Plateletworks Arachidonic Acid Kit contains 25 baseline tubes (contain K3 EDTA) and 25 ACA tubes (arachidonic acid isolated from porcine liver) and a % Aggregation/Inhibition chart.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Arachidonic Acid

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

K912774

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	<i>Plateletworks Arachidonic Acid</i>	<i>Arachidonic Acid</i>
Intended Use	For the qualitative determination of platelet inhibition by aspirin which inhibit arachidonic acid induced platelet aggregation. The change in platelet count due to activation and aggregation of functional platelets is measured using an electronic impedance-based cell counter.	For use in platelet aggregometry studies.

Differences		
Item	Device	Predicate
	<i>Plateletworks Arachidonic Acid</i>	<i>Arachidonic Acid</i>
Function	Measures aggregation of platelets in response to an agonist using impedance hematology counter to measure aggregation	Measures aggregation of platelets in response to an agonist using light transmission to measure aggregation.
Sample	Citrated whole blood	Citrated platelet rich plasma
Measurement	Screening (qualitative)	Direct measurement (quantitative)

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

EP5A Evaluation of Precision Performance of Clinical Chemistry Device Approved Guideline, NCCLS

L. Test Principle:

Traditional platelet aggregometry, the reference method for testing platelet function, is based on the addition of the platelet agonist to a blood sample (usually platelet rich plasma). Platelet aggregation may be assessed using various agonists such as ADP, collagen, and others. Arachidonic acid is a fatty acid which is liberated from the human platelets on activation and is converted by the enzyme cyclooxygenase into a potent inducer of platelet aggregation. Ingestion of aspirin or other similar drugs inhibits cyclooxygenase-1 (COX-1) thus inhibiting platelet aggregation.

The Plateletworks methodology is an adaptation of platelet aggregometry that is extremely simple, inexpensive, and quick to perform. This two step method involves using a cell counter to measure total platelet count in a whole blood sample and to re-determine the platelet count on a second sample that has been exposed to a known platelet agonist. The agonist will stimulate those platelets which are functional to aggregate into clumps and they will not be counted as platelet in the second sample. The difference in the platelet count between samples one and two provides a direct measurement of platelets aggregation and is reported as percent aggregation.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision was determined by testing an aspirin donor (in duplicate) for 10 days, 1 run per day. Results are as follows:

Within run CV = 23.0% Total SD = 6.7

Lot to lot reproducibility was evaluated using normal and abnormal donors on six product lots. Results were acceptable.

b. *Linearity/assay reportable range:*

Not applicable.

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

Data to support stability was provided for six lots. Normal donors were used for testing and 60% or greater aggregation was detected. A nine month shelf-life was assigned.

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*

Not applicable.

f. *Assay cut-off:*

Not applicable.

2. Comparison studies:

Not applicable.

a. *Method comparison with predicate device:*

Not applicable.

b. *Matrix comparison:*

Not applicable.

3. Clinical studies:

Correlation studies were performed by testing male and female adults, greater than 18 years of age, at four clinical sites with two laboratory methods: Reference – LTA (Light Transmission Aggregometry) and Test – PW-ACA. The subjects included normal, healthy individuals, in addition to, patients and individuals that were taking aspirin (325 mg, 162 mg, and 81 mg).

Comparison of two Laboratory Methods

		95% confidence limits
Agreement	87.54 %	(83.53 to 90.87%)
Positive Agreement	93.20 %	(86.50-97.22%)
Negative Agreement	85.04%	(79.82-89.35%)

a. *Clinical Sensitivity:*

Plateletworks ACA with aspirin and non aspirin donors: **0.970**

b. *Clinical specificity:*

Plateletworks ACA with aspirin and non aspirin donors: **0.875**

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

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Normal donors (173), who had not taken aspirin or other medications (which inhibit platelet aggregation), were tested and a normal range was determined with a cut off value of $\geq 60\%$. The same donors were tested with Light Transmission Aggregometry (LTA). The recommended range of 60-100% compensates for the qualitative/screening nature of the test system.

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 substantial equivalence decision.

