

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

A. 510(k) Number: #K032951

B. Analyte: Platelet aggregometry

C. Type of Test: Quantitative

D. Applicant: Chrono-log Corporation

E. Proprietary and Established Names: Whole Blood Aggregometer (WBA), Model 591A/592A

F. Regulatory Information:

1. Regulation section: CFR Section 864.5700 – Automated Platelet Aggregation System
2. Classification: Class II
3. Product Code: JOZ
4. Panel: Hematology (81)

G. Intended Use:

1. Intended use(s):
The Chrono-log Whole Blood Aggregometer (WBA) Model 591A/592A is intended for determination of platelet function in a whole blood specimen, using ADP, Collagen and Ristocetin reagents.
2. Indication(s) for use: The Chromo-log WBA Model 591A/592A is for platelet function testing of whole blood specimens using Impedance Aggregometry.
3. Special condition for use statement(s): N/A
4. Special instrument Requirements: N/A

H. Device Description: The Model 591A/592A WBA is a modified version of their single and dual channel Model 591/592 WBA. The new model employs the use of a gold plated disposable electrode, while the current model uses a palladium reusable electrode. Other changes are the probe's method of connection, size and square shape, instead of the round shape of the reusable electrode. The disposable probe is not for use with the agonist, Arachidonic Acid (AA), as is the reusable electrode.

I. Substantial Equivalence Information:

1. Predicate device name(s): Chrono-log WBA, Model 591/592
2. Predicate K number(s):
#K962426
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Principle of Operation	Electrical impedance	Same
Sample type	Citrated whole blood	Same
Calibration	Electrical	Same
Channels	Single and dual	Same
Test results	Ohms	Same
Readout	Digital w/optical chart reader	Same
Differences		
Item	Device	Predicate
Type/shape of electrode	Gold plate/square	Palladium/round
Method of connection	Attached to copper traces embedded on a flexible Kapton sheet	Soldered to a printed circuit board, coated with non-conductive polyurethane
Size of electrode	0.01 x 0.01 x 0.2 inches	0.01 x 0.24 inches
Agonists used	Only ADP, Collagen and Ristocetin	Arachidonic acid, ADP, Collagen and Ristocetin

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

K. Test Principle: Both Models of the Chrono-log WBA use electrical impedance to measure platelet aggregation in citrated whole blood. The electrode assembly is placed into a cuvette containing whole blood, and is then heated to 37° C. A stirbar is spun to stir the sample, during which a layer of platelets builds up on the electrode pins. The electric circuit monitors the current in the sample, and upon stabilization, a baseline is established. The circuit converts the current into an impedance measurement. The agonist is added to the sample, upon which platelets aggregate and gather on the electrode tip. The sample current is reduced and converted, by the circuit, into an impedance change. That change is directly related to the amount of aggregation in the sample. It is then converted into a numeric readout, as a change of impedance in Ohms, or recorded on a strip chart recorder.

L. Performance Characteristics (if/when applicable): N/A

1. Analytical performance:

- a. *Precision/Reproducibility:*
- b. *Linearity/assay reportable range:*
- c. *Traceability (controls, calibrators, or method):*
- d. *Detection limit:*
- e. *Analytical specificity:*
- f. *Assay cut-off*

2. Comparison studies:

- a. *Method comparison with predicate device:* A clinical probe comparison study was performed at Miriam Hospital on whole blood samples (N=50) from normal subjects, using all agonists. Females (N=35) and males (N=15) yielded correlation between the two probes of $r = 0.79$. The 'p' value was < 0.01 .

An additional comparison study between the two electrodes, using ADP and collagen on normal samples (N = 250), was performed. That study yielded $r = 0.84$; and a 'p' value of < 0.0001 .

- b. *Matrix comparison:* A study performed with disposable and reusable electrodes in whole blood (WB) and platelet rich plasma (PRP) samples (with decreasing platelet counts) generated these results:

WB - $R^2 = 0.9037$ (Disposable); $R^2 = 0.4491$ (Reusable)
 PRP - $R^2 = 0.8512$ (Disposable); $R^2 = 0.9064$ (Reusable)

3. Clinical studies:a. *Clinical sensitivity:*b. *Clinical specificity:*c. *Other clinical supportive data (when a and b are not applicable):*

The company also supplied studies of the probes in normal samples, along with Bland-Altman plots, using ADP and collagen agonists; and with the Ristocetin agonist in patients with von Willebrand Disease (vWD) to demonstrate the probe's sensitivity to von Willebrand Factor deficiency.

4. Clinical cut-off: 5 Ohms

5. Expected values/Reference range: The normal range study for the disposable electrode was performed on donors (N = 50), with agonists ADP, collagen and Ristocetin. The following results were not significantly different from the reusable electrode's reference values:

<u>Agonist</u>	<u>Concentration</u>	<u>Aggregation (Ohms)</u>
<u>ADP</u>	20 uM	9 – 10
<u>Collagen</u>	5 ug/mL	12 – 23
<u>Ristocetin</u>	0.4 mg/mL	> 5

M. Conclusion:

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