

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

A. 510(k) Number:

K050265

B. Purpose for Submission:

New instrument

C. Manufacturer and Instrument Name:

CHRONO-LOG Corporation, Model 700 Whole Blood Lumi-Aggregometer

D. Type of Test or Tests Performed:

Platelet Function Assays: Collagen, ADP, Arachidonic Acid, Epinephrine, Ristocetin, Thrombin

E. System Descriptions:

1. Device Description:

The Chrono-log Model 700 aggregometer measures platelet function on patient samples using electrical impedance in whole blood or optical density in plasma. The Model 700 Aggregometer has the capability to simultaneously measure ATP release with either method using luminescence. The 700 Aggregometer is also used to run the Ristocetin Cofactor Assay which is used to diagnose patients with von Willebrands disease. The instrument comes with a starter kit consisting of the following Chrono-log reagents and supplies: ADP, Arachidonic Acid, Collagen, Epinephrine, Ristocetin, Thrombin, a CHRONO-LUME kit, a Ristocetin Cofactor Kit, cuvettes, stir bars and pipettes. The output of the Model 700 can be connected to either a strip chart recorder or to a computer. Software is provided for computer interface option. The computer interface option is used to collect data only. The computer is not used for diagnosis or treatment and does not have any control over or input into the Model 700 Aggregometer.

2. Principles of Operation:

The Chrono-log Model 700 measures platelet aggregation either photometrically using Platelet Rich Plasma (PRP) or by measuring change in electrical impedance in whole blood. The rate and the degree of aggregation are plotted using a recording device. Platelet aggregation in vitro is dependent on calcium ions. The Chrono-log

Model 700 utilizes two methods, Impedance and Luminescence.

Impedance Method (or electrical resistance) method of aggregation is non-optical. An electrode probe assembly is inserted into a cuvette containing a whole blood test sample. This method for measuring platelets aggregation allows the study of platelets in the more physiologic whole blood environment.

Luminescence Method: ATP release is measured by a luminescence technique in PRP or whole blood. The principle of the Lumi-Aggregometer is to measure secretion by a sensitive luminescent assay for extra-cellular ATP in combination with the simultaneous measurement of aggregation.

3. Modes of Operation:

Semi-Automated. The output of the Model 700 can be connected to either a strip chart recorder or to a computer. Software is provided for computer interface option. The computer interface option is used to collect data only.

4. Specimen Identification:

When using the ACCRO/LINK, a new file is generated for each patient with name, identification (file name) and date at the beginning of each new run.

5. Specimen Sampling and Handling:

(1 or 2) 4.5 ml Whole blood with 3.2% or 3.8% sodium citrate at room temperature.

(5) 4.5 ml blue top tube for PRP at room temperature

An EDTA blood specimen must be collected from the patient for hematocrit and platelet count.

Plastic or non-contact surfaced (siliconized) materials should be used throughout in order to minimize activation of the platelets during sample preparation.

Testing can be performed up to 3 hours after venipuncture

6. Calibration:

Impedance: Set Baseline Button automatically sets Zero Baseline and Gain

Luminescence: Baseline is set automatically. Calibrate ATP Secretion with a 2 nM ATP Standard

7. Quality Control:

A drug free normal control whenever reagents are reconstituted or thawed. This result should be within laboratory established values.

Positive controls can be provided by collecting samples from aspirin volunteers and previously diagnosed patients with platelet disorders or by adding aspirin to depleted plasma to a final concentration of 1 mM aspirin in citrated blood.

8. Software:

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

Yes ___ X ___ or No _____

F. Regulatory Information:

1. Regulation section:

CFR 864.5700

2. Classification:

Class II

3. Product code:

JOZ

4. Panel:

Hematology - 81

G. Intended Use:

1. Indication(s) for Use:

For in-vitro diagnostic use for measuring platelet aggregation and ATP secretion in whole blood or platelet rich plasma

2. Special Conditions for Use Statement(s):

None

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

k830749-Chrono-log Model 560 Aggregometer with AGGRO/LINK Interface;

k032951-Chrono-log Whole Blood Aggregometer Model 591A/592A

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Principles of Operation	Electrical Impedance, turbidometric measurement in PRP and simultaneous measurement of ATP release	Same
Instrument Calibration	Impedance-confirmed electrically prior to the start of each assay. Auto calibration for the Optical Method Luminescence uses a 2nmole standard	Same
Specimen Type	Whole Blood or Platelet Rich Plasma	Same
Method of Reporting	Chart Recorder or Computer Interface with AGGRO/LINK Software	Same
Reporting Units	Ohms for Whole Blood Percent for PRP Nanomole for ATP Release	Same

Differences		
Item	Device	Predicate
No. of Channels	2 or 4	2

I. Special Control/Guidance Document Referenced (if applicable):

None

J. Performance Characteristics:

1. Analytical Performance:

a. *Accuracy:* Not applicable

b. *Precision/Reproducibility:*

Optical: Using 2ug/mL of collagen for four replicate runs, three operators

$Sd^2 = 7.08$, $S=2.66$

Impedance: Using 5ug/mL of collagen, four replicate runs, three operators

$Sd^2 = 3.95$, $S=1.99$

Luminescence: run simultaneously with both impedance and optical

$Sd^2 = 1.01$, $S=0.08$ Impedance, $Sd^2 = 0.93$, $S=0.08$ Optical

c. *Linearity:*

Platelet samples were run using various dilutions of normal plasma were used to obtain the full measure range of the assay. Two replicates were run at each plasma levels with dilutions 1:1.6, 1:3.2, 1:4.8, and 1:6.4.

Optical Linearity: $R^2 = 0.9883$

Impedance: $R^2 = 0.9188$, $R^2= 0.9917$

Luminescence: $R^2 = 0.9891$

d. *Carryover:*

Not applicable

e. *Interfering Substances:*

List referenced literature

2. Other Supportive Instrument Performance Data Not Covered Above:

Correlation with Model 560

Impedance: $r = 0.7612$ (sample size 71); $r = 0.7863$ (sample size 196)

$R = 0.8925$ (sample size 8)

Luminescence: $r = 0.7260$ (sample size 71); $r = 0.7286$ (sample size 228)

$r = 0.6669$ (sample size 103);

Optical: $r = 0.7725$ (sample size 89); $r = 0.6669$ (sample size 103)

$R = 0.7652$ (sample size 105)

Chrono-Log Aggregation Probe Comparison Study: to compare the aggregation responses in whole blood using the reusable probe and the new disposable probes. The study consisted of 50 normal healthy human subjects with a mean age of 42 ± 10.9 years, male and females, platelet count was 247 ± 53 .

$R = 0.79$, $p < 0.1$

K. Proposed Labeling:

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

L. Conclusion:

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