

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

A. 510(k) Number:

K032952

B. Analyte:

Activated Clotting Time

C. Type of Test:

Quantitative

D. Applicant:

Sienco, INC

E. Proprietary and Established Names:

Sienco aiACT Kit

F. Regulatory Information:

1. Regulation section:
21 CFR 864.7140
2. Classification:
Class II
3. Product Code:
JBP- Activated Whole Blood Clotting
4. Panel:
81 Hematology

G. Intended Use:

1. Indication(s) for use:
The aiACT Kit is an *in vitro* diagnostic test for use with the Sonoclot® Coagulation & Platelet Function Analyzer System. The aiACT test is an activated whole blood clotting time test which uses a blend of celite and clay for contact activation. It may also be used with citrated whole blood.
2. Special condition for use statement(s):
The aiACT Kit is intended only for high dose heparin anticoagulation management (ACT \geq 400 seconds on Sonoclot Analyzer) as typical encountered during cardiopulmonary bypass surgery. The aiACT test provides ACT results that are substantially unaffected by aprotinin.
3. Special instrument Requirements:
Sienco Sonoclot Analyzer

H. Device Description:

The Sienco aiACT Kit contains yellow plastic activation cuvettes and probes. The activation cuvettes contain a controlled amount of contact activator and a magnetic stir bar.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Sienco SonACT Kit
2. Predicate K number(s):
K952560
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Instrument requirements	Sonoclot coagulation & Platelet Function Analyzer	Same
Test design	Plastic lidded cuvette containing contact activator and magnetic stir bar	same
Differences		
Item	Device	Predicate
Intended use	High dose heparin anticoagulation management, especially in the presence of aprotinin	General purpose global homeostasis monitoring, hypercoagulable and hyperfibrinolysis screening, platelet function assessment, anticoagulation management (low to high heparin levels)
Activator	Celite and clay mixture	celite
Results provided	Quantitative results for Activate Clotting Time (Sonoclot Onset Time) and rate of fibrin polymerization (Sonoclot clot Rate)	Quantitative results for Activated Clotting Time (Sonoclot Onset Time ⁰ and rate of fibrin polymerization (Sonoclot Clot Rate). Qualitative and quantitative platelet function information (time to peak, clot retraction)

J. Standard/Guidance Document Referenced (if applicable):**K. Test Principle:**

The Sienco aiACT measures the amount of time it takes to form a clot by contact activation of the coagulation cascade.

In surgeries requiring the use of extracorporeal circuits, such as cardiopulmonary bypass, the anticoagulant drug heparin is administered to prevent blood clots from forming while blood is flowing through the circuit. The activated clotting time (ACT) is measured to monitor the anticoagulant effect of heparin. A baseline ACT is measured before heparinization, and heparin levels are monitored throughout surgery to maintain sufficient anticoagulation.

Aprotinin is administered during surgery to reduce blood loss after CPB surgery, and generally prolongs ACT results for celite, kaolin, and glass bead activated ACT assays. This prolongation of ACT results may pose a risk of under heparinization and subsequent clotting during surgery. The Sienco aiACT has been formulated to be relatively insensitive to aprotinin, thus allowing for improved management of heparinized patients taking aprotinin.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

5 Sonoclot Analyzer Systems were run on three normal native whole blood samples using the aiACT test. CV's were $\leq 10\%$.

b. *Linearity/assay reportable range:*

c. *Traceability (controls, calibrators, or method):*

d. *Detection limit:*

e. *Analytical specificity:*

Heparin sensitivity- Heparin dose response curves were collected on 3 normal donors for the aiACT activated SonACT test. The test demonstrated a linear relationship between ACT results and heparin levels.

Aprotinin interference- effect of native whole blood spiked with 160, 320, and 500 IU Aprotinin on the KACT, aiACT, and celite ACT assays. Results demonstrated that aprotinin will not alter the average ACT result by more than 15% for aprotinin levels up to 320 KIU/ml.

f. *Assay cut-off:*

N/A

2. Comparison studies:

a. *Method comparison with predicate device:*

3 site clinical study. N=90, data collected at for native whole blood ($y=1.1096X + 0$), and citrated ($y=1.0269X + 0$) whole blood at baseline, after heparinization, periodically whole on pump and after heparin reversal.

b. Matrix comparison:

3. Clinical studies:

a. Clinical sensitivity:

b. Clinical specificity:

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

4. Clinical cut-off:

5. Expected values/Reference range:

Native blood from 21 normal donors was run on the aiACT. Statistical analysis was performed on ACT/onset and Clot Rate parameter results, and normal ranges established.

M. Conclusion:

Based on acceptable performance data, I find this device substantially equivalent to a legally marketed device.