

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

A. 510(k) Number:

K060688

B. Purpose for Submission:

Special submission for a modification to the APTT parameter settings for HemosIL SynthASil on the ACL Futura and ACL Advance which allows for improved correlation with the ACL TOP

C. Analyte:

Activated Partial Thromboplastin Time (APTT)

D. Type of Test:

Clotting

E. Applicant:

Instrumentation Laboratories

F. Proprietary and Established Names:

HemosIL SynthASil

G. Regulatory Information:

1. Regulation section:
21 CFR 864.7925
2. Classification:
Class II
3. Product Code:
GFO
4. Panel:
81 Hematology

H. Intended Use:

1. Intended use(s):
The HemosIL SynthASil is a high quality synthetic phospholipid reagent for the *in vitro* determination of Activated Partial Thromboplastin Time (APTT) in human citrated plasma on IL Coagulation and ELECTRA Systems
2. Indication(s) for use:
3. Special condition for use statement(s):
4. Special instrument Requirements:
IL Coagulation and ELECTRA Systems

I. Device Description:

The HemosIL SynthASil is a phospholipid reagent for the *in vitro* determination of APTT in human citrated plasma. It is used for the evaluation of the intrinsic coagulation pathway, and the monitoring of heparin therapy.

J. Substantial Equivalence Information:

1. Predicate device name(s):
HemosIL SynthASil

2. Predicate K number(s):
K953981
3. Comparison with predicate:

| Similarities | | |
|----------------------------|---|------------------|
| Item | Device | Predicate |
| Intended Use | Hemosil SynthASil is a high quality synthetic phospholipid reagent for the <i>in vitro</i> determination of APTT in human citrated plasma on IL Coagulation and ELECTRA Systems | same |
| Test Principle | When sample testing is initiated, sample, APTT reagent, a negatively charged contact activator and buffer are incubated at 37°C for a specific period of time which initiates the activation of the intrinsic coagulation pathway. Calcium is then added to trigger the coagulation process and the time required for clot formation is measured. | same |
| Differences | | |
| Item | Device | Predicate |
| Normalized Curve Smoothing | 1 | 9 |
| Offset % | 67 | 35 |

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

L. Test Principle:

See table above

M. Performance Characteristics (if/when applicable):

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:

b. Matrix comparison:

3. Clinical studies:

a. Clinical sensitivity:

b. Clinical specificity:

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

As required for a Special 510(k), the Sponsor has provided a risk analysis as well as a Declaration of Conformity with Design Controls indicating that development activities were conducted under appropriate design controls procedures, and the overall product specifications were met.

4. Clinical cut-off:

5. Expected values/Reference range:

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision for a “special” submission.