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

A. 510(k) Number:
K033414

B. Instrument Name:
ACL TOP

C. System Descriptions:
1. Modes of Operation:
   Automated, random access

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:
   Yes ____X____ or No _____

3. Sample Identification:
   Samples, reagents and diluents are identified by a bar code reader

4. Specimen Sampling and Handling:
   Samples- either open tube or plasma aliquoted into sample cups. A sample probe aspirates and dispenses materials from sample racks

5. Assay Types:
   The ACL TOP is capable of performing the following coagulation assays: Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen (Clauss and PT-based), D-Dimer, Protein C, Antithrombin and Intrinsic and Extrinsic Factor Assays

6. Reaction Types:
   The ACL TOP performs coagulometric (turbidimetric), chromogenic (absorbance), and immunological measurements

7. Calibration:
   Commercially available Assess Calibration Plasma (K002400)

8. Quality Control:
   Allows for programming to automatically execute QC or generate a prompt when QC is due, when QC material has expired, or when QC has failed

D. Other Supportive Performance Characteristics Data Not Covered In The "L. Performance Characteristics" Section Of The SE Decision Summary.
The submission is an abbreviated 510(K) submitted in compliance to the *guidance for Industry and FDA Staff- 510(k) Submissions for Coagulation Instruments*

Additional performance studies:

Onboard stability- To demonstrate that stability claim for manufactured liquids are met or exceeded. Analytical testing was performed, at suitable intervals, for longer than the expected stability of the reagent using validated controls. The percent recovery compared to the mean obtained using fresh material was evaluated.

Sample Carryover- samples of high concentration of analyte were analyzed prior to samples of low concentration of analyte. Test conditions: 4 replicates of analyte/run with no contamination present, 4 replicates contaminate samples/run, 8 replicates of recipient samples/run, 1 run/day over 1 day, 2 instruments. The percentage change of the recipient sample mean from the baseline mean was evaluated.

Reagent Carryover- Evaluated the effect observed when other reagents used by the system contaminate components of the system or test method. Reagent-to-reagent carryover for each contaminating reagent was tested for each test reagent. Test conditions: 8 replicates of analyte/run with no contamination present, 8 replicates contaminate reagent/run, 8 replicates of recipient analyte/run, 1 run/day over 1 day, 2 instruments. The percentage change of the recipient sample mean from the baseline mean was evaluated.

Parallelism Precision (factor Assays) - Factor precision was performed in accordance with NCCLS document H48-A for each of the extrinsic factors using the parallelism function of the ACL TOP.

Detection Limit (D-Dimer)- Detection limit studies for D-Dimer were performed on two ACL TOP analyzers by analyzing Factor Diluent (saline) in a run of twenty replicates on two ACL TOP Analyzers. The mean plus 3 SD was calculated and the maximum value was added to the reagent labeling.

Prozone (D-Dimer)- Dilutions of a prozone control containing a high concentration of D-Dimer (~100000 ng/mL) were prepared and analyzed in replicates of four on two ACL TOP analyzers. No prozone effect was seen up to 100000 ng/mL)

E. **Other Supportive Information:**

Heparin Response Curve (APTT) – One lot of HemosIL SynthASil (APTT) (K953981) reagent spiked with graduated quantities of unfractionated heparin and tested. The data demonstrates a heparin response on the act top to 0.8 U/mL.

A Replacement Reagent Protocol was submitted to include:

Protocols for within run and total precision, method comparison, linearity, carryover interference, stability, target medical decision levels.

F. **Conclusion:**

Based on acceptable performance, this device is found substantially equivalent to the predicate device (ACL Advance K002400).