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BEHRING

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
For ProC APC

1. **Manufacturer and Contact Information:**

Manufacturer: Behringwerke AG
Postfach 1140
35001 Marburg, Germany

Contact Information: Paul Rogers
Behring Diagnostics Inc.
3403 Yerba Buena Road
P.O. Box 49013
San Jose, CA 95161-9013
Tel: 408-239-2000

2. **Device Classification Name:**
The ProC APC is a Class II device and has a classification name of partial thromboplastin time test (21 CFR §864.7925).

3. **Intended Use:**
ProC APC is intended for the determination of the activated Protein C sensitivity of the activated partial thromboplastin time (aPTT) in citrated human plasma.

4. **Device Description and Characteristics:**
The ProC APC assay consists of a liquid aPTT Reagent (containing phospholipids, silica-based activator), a lyophilized activated Protein C time (APCT) Reagent (containing activated human Protein C), and lyophilized Control Plasma (in the pathological range). This is similar to the Chromogenix Coatest APC Resistance-C (Coatest APC) assay, the predicate device, which consists a liquid aPTT reagent (phospholipids, silica-based activator), a lyophilized APC/CaCl2 reagent (activated human Protein C), and two lyophilized Control Plasmas (for normal and pathological ranges).

Comparative Analysis: A total of 116 plasma samples (22 Factor V Leiden carriers, 94 normal blood donors) were tested by the ProC APC and the Coatest APC Resistance-C. The ProC APC correctly identified the 116 samples as either having normal or abnormal (Factor V Leiden) APC sensitivities. The Coatest APC identified 20 of the 22 Factor V Leiden samples as having abnormal APC sensitivities and 92 of the 94 normal blood donor samples as having normal APC sensitivities.

Precision: Precision studies were performed following the NCCLS EP5 guideline using two plasma samples which were in the normal and abnormal APC sensitivity ranges. The within-run precision ranged from 1.7 to 2.9%. The total precision ranged from 2.5 to 7.3%.

5. **Substantial Equivalence:**
Behring Diagnostics Inc. considers the ProC APC to be substantially equivalent to the Chromogenix Coatest APC Resistance-C in terms of intended use, reagent composition, and overall performance characteristics.