

APR - 3 1996

**510(k) Summary of Safety and Effectiveness**

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**Names of Device:**  
Trade Name: Calibration Verification Assessment (CVA)  
Common Name: Assayed hematology control  
Classification Name: Hematology quality control mixture (§864.8625)

**Predicate Device:** CBC-LINE (K942822) R&D Systems, Inc.

**Description:** CVA is a suspension of stabilized human red blood cells, human white cells, and simulated platelets (from mammalian red blood cells) packaged as separate components. CVA is supplied in glass vials containing 2.0 mL volumes. Closures are injection molded polypropylene screw-top caps. The vials are packaged in polystyrene jars.

**Intended Use:** CVA is a calibration (linearity) assessment kit which contains white blood cell (WBC), red blood cell/hemoglobin (RBC/Hgb), and platelet (PLT) concentrations across the reportable ranges recommended by CLIA (the Clinical Laboratory Improvement Act). It is intended to allow users to satisfy CAP requirements and CLIA recommendations to verify patient reportable ranges.

**Comparison with Predicate Device:**

Parameter	CVA	CBC-LINE
WBC range	0.5 - 90 × 10 <sup>9</sup> /L	9.0 - 90 × 10 <sup>9</sup> /L
RBC range	0.4 - 7.2 × 10 <sup>12</sup> /L	1.6 - 7.6 × 10 <sup>12</sup> /L
PLT range	15 - 900 × 10 <sup>9</sup> /L	100 - 1100 × 10 <sup>9</sup> /L
HgB range	1.2 - 22 g/dL	4.5 - 23 g/dL
separate components	yes	yes
number of levels	four	six
assayed	yes	no

**Discussion of Tests and Test Results:** Three studies of CVA were conducted: I) lot to lot reproducibility; II) within lot reproducibility and comparison with predicate product & whole blood; and III) long term and open vial stability. Study results showed CVA to be consistently reproducible, substantially equivalent to the predicate product, and stable for the entire product dating

**Conclusions Drawn from Tests:** CVA is a safe and effective hematology control when used as instructed in the product package insert.