

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

A. 510(k) Number:

K041130

B. Purpose for Submission:

New device

C. Analyte:

Red Blood Cells, White Blood Cells, Platelets, Hemoglobin

D. Type of Test:

Instrument Calibration

E. Applicant:

Clinical Diagnostics Solutions, Inc.

F. Proprietary and Established Names:

CDS Hematology Calibrator

G. Regulatory Information:

1. Regulation section:

864.8150

864.8165

864.8175

864.8185

2. Classification:

Class II

3. Product Code:

KRZ, KRY, KSA

4. Panel:

Hematology (81)

H. Intended Use:

1. Intended use:

CDS Hematology Calibrator is intended to be used as a calibrator for WBC, RBC, HGB, MCV and PLT parameters on impedance based hematology instruments such as:

Abbott: CD1400, CD1600, CD1700, CD1800

CDS Hematology Calibrator is intended to be used as a calibrator for WBC, RBC, HGB, MCV, PLT, and MPV parameters on impedance based hematology instruments such as:

ABS: Micros

Beckman Coulter: STKS, MAXM, STKR, S-Plus Series, MD, OnyX, T, JT, Ac●T
 Boule: CA530/620
 Danam: Excell 16
 Sysmex K series

2. Indication for use:

CDS Hematology Calibrator for red cell, white cell and platelet counting is a device that resembles red cells, white cells and platelets in whole blood specimens and is intended to serve as a calibration standard for automated hematology analyzers, including Beckman Coulter S Plus II-VI series, STKR, JS, JR, ST, and JT series, STKS, MAXM, HmX, Gen● S, MD series, OnyX, T series and A^c ●T and A^c ●T diff series analyzers; the Abbott Cell-Dyn 1400, 1500, 1600 and 1700 analyzers; and the Danam EXCEL 16 and EXCEL 22 analyzers intended to count red cells, white cells and platelets. It is a suspension of particles or cells whose size, shape, concentration and other characteristics have been precisely and accurately determined.

3. Special condition for use statement(s):

Not applicable

4. Special instrument Requirements:

CDS Hematology Calibrator serves as a calibration standard for automatic hematology analyzers, including Beckman Coulter S Plus II-VI series, STKR, JS, JR, ST, and JT series, STKS, MAXM, HmX, Gen● S, MD series, OnyX, T series and A^c ●T and A^c ●T diff series analyzers; the Abbott Cell-Dyn 1400, 1500, 1600 and 1700 analyzers; and the Danam EXCEL 16 and EXCEL 22 analyzers.

I. Device Description:

CDS Hematology Calibrator is a suspension of stabilized human red blood cells, stabilized white cells or surrogates of human or animal origin and stabilized platelets or surrogates of animal origin, suspended in a synthetic plasma-like solution. The size, shape and concentration of the cells in the suspension have been precisely and accurately determined. Each calibrator is supplied with assay values assigned by a procedure tied to standard reference methods. The calibrator is supplied in glass tubes with polypropylene screw caps. The tubes are packaged in PVC clamshells.

J. Substantial Equivalence Information:

1. Predicate device names:

Streck Cal Chex
 R&D CBC Cal Plus
 Coulter S-Cal

2. Predicate K numbers:

K840261

K897060

K862122

3. Comparison with predicate:

Similarities				
Item	Device	Predicates		
	<i>CDS Cal</i>	<i>Streck Labs Cal Chex</i>	<i>R&D Systems CD-CAL</i>	<i>Beck-Coulter S-Cal</i>
RBC	Human RBC	Same	Same	Same
Differences				
Item	Device	Predicate		
	<i>CDS Cal</i>	<i>Streck Labs Cal Chex</i>	<i>R&D Systems CD-CAL</i>	<i>Beck-Coulter S-Cal</i>
WBC	Human /Animal RBC	Human WBC	Animal WBC	Human/ Animal RBC
PLT	Animal RBC	Animal RBC	Animal PLT	Animal RBC

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

H15-A02 *Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard-Third Edition, NCCLS*

Hemoglobin value is traceable to ICHS HiCN Standard

H07-A02 *Procedure for Determining Packed Cell Volume by the Microhematocrit Method-Third Edition; Approved Standard, NCCLS*

L. Test Principle:

The calibration procedure uses replicates of the calibrator run on a hematology instrument to provide an average result for each parameter (WBC, RBC, HGB, MCV, PLT, MPV). The average values are then compared to published assay values for the specific lot of calibrator. If the results are outside of the published tolerance range, the instrument calibration can be adjusted to meet these values

M. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

A 15 sample precision study was performed comparing fresh blood to a CDS calibrator (Lot #2).

	WBC CV	RBC CV	HGB CV	HCT CV	MCV CV	PLT CV	MPV CV
Fresh Blood Sample	0.17	0.05	0.11	0.62	0.97	8.57	0.26
CDS Calibrator	0.15	0.04	0.09	0.34	0.32	6.88	0.29

- b. *Linearity/assay reportable range:*
N/A
- c. *Traceability (controls, calibrators, or method):*
N/A
- d. *Detection limit:*
N/A
- e. *Analytical specificity:*
N/A
- f. *Assay cut-off:*
N/A

2. Comparison studies:

- a. *Method comparison with predicate device:*
A study was performed comparing fresh blood reference calibration with 2 predicate calibrators and three lots of CDS calibrator, which were manufactured at different times using different raw materials. The calibrators were run on two instruments (Coulter A^c •T and Abbott CD1700). The assigned assay values were compared to the average value recovered from a calibration run. The results for the commercial calibrators were equivalent to the reference methodology.
- b. *Matrix comparison:*
N/A

3. Clinical studies:

- a. *Clinical sensitivity:*
N/A
- b. *Clinical specificity:*
N/A
- c. *Other clinical supportive data (when a and b are not applicable):*
N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

Value assignment data and the value assignment protocol were provided.

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.