

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

A. 510(k) Number:

K042587

B. Purpose for Submission:

New device

C. Analyte:

Reticulocyte

D. Type of Test:

Quantitative

E. Applicant:

Streck Laboratories

F. Proprietary and Established Names:

Retic-Chex for Cell-Dyn®

G. Regulatory Information:

1. Regulation section:
21 CFR 864.8625, Hematology quality control mixture
2. Classification:
Class II
3. Product Code:
JPK, Mixture, Hematology quality control
4. Panel:
Hematology (81)

H. Intended Use:

1. Intended use(s):
Retic-Chex for Cell-Dyn is an assayed control for evaluating the accuracy and precision of automated, semi-automated, and manual methods of reticulocyte counting.
2. Indication(s) for use:
Retic-Chex for Cell-Dyn is an assayed control for evaluating the accuracy and precision of automated, semi-automated, and manual methods of reticulocyte counting.

3. Special condition for use statement(s):
Not applicable
4. Special instrument Requirements:
Retic-Chex is designed for use on the following reticulocyte analyzers: Abbott Cell-Dyn 3200, 3500/3700 and 4000.

I. Device Description:

Retic-Chex for Cell-Dyn is a suspension of stabilized human red blood cells and simulated human reticulocytes packaged in plastic vials containing 1.0 ml volumes. The device consists of two levels of reticulocyte percentage range. Control I reticulocyte percent range will be 1.5-2.0. Control II reticulocyte percent range will be 3.9-5.8. Closures are injection molded polypropylene screw-top caps. The vials are packaged in a vacuum molded clam-shell box.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Retic-Chex® Linearity
2. Predicate K number(s):
K000115
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	<i>Retic-Chex for Cell-Dyn®</i>	<i>Retic-Chex Linearity</i>
Intended Use	Used as an assayed control for evaluating the accuracy and precision of automated, semi-automated, and manual methods of reticulocyte counting.	Same
Contents	Stabilized human red blood cells	Same
Analyzers	Abbott Cell-Dyn 3200, 3500/3700, and 4000	Abbott Cell-Dyn 3500/3700 and 4000 Bayer Advia 120 Beckman STKS/MAXM/HmX Sysmex R-3000/R-3500/R-1000/RAM-1 XE-2100 XT-2000i

Differences		
Item	Device	Predicate
Control Levels	Two levels	Five levels
Stability	55 days after shipping 14 days after opening	45 days after shipping 5 days after opening

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

Not provided

L. Test Principle:

Laboratories require material for quality control of automated, semi-automated, and manual procedures that measure whole blood parameters.

Use of stabilized cell preparations for controlling laboratory testing is an established procedure. When handled like a patient sample and assayed on a properly calibrated and functioning instrument or manual methods, the whole blood control will provide values within the expected range indicated on the assay sheet.

M. Performance Characteristics (if/when applicable):1. Analytical performance:

- a. *Precision/Reproducibility:*
Not applicable
- b. *Linearity/assay reportable range:*
Not applicable
- c. *Traceability (controls, calibrators, or method):*
Not applicable
- d. *Detection limit:*
Not applicable
- e. *Analytical specificity:*
Not applicable
- f. *Assay cut-off:*
Not applicable

2. Comparison studies:

- a. *Method comparison with predicate device:*
Not applicable
- b. *Matrix comparison:*
Not applicable

3. Clinical studies:

- a. *Clinical sensitivity:*
Not applicable
- b. *Clinical specificity:*
Not applicable

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

4. Clinical cut-off:
Not applicable
5. Expected values/Reference range:
Control values should fall within the Expected Range indicated on the accompanying assay sheet. Upon receipt of a new control lot, it is recommended that each individual laboratory establish its own mean limits for each parameter.

N. Conclusion:

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

