510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE TEMPLATE

A. 510(k) Number: k040025

B. Analyte: HbA1c

C. Type of Test: N/A

D. Applicant: Streck Laboratories

E. Proprietary and Established Names: A1c-Chex

F. Regulatory Information:

1. Regulation section: 21 CFR 862.1660

2. Classification: Class I

3. Product Code: JJX

4. Panel: 75

G. Intended Use

1. Intended use(s): See indications for use.

2. Indication(s) for use:

A1c-Chex is a bi-level whole blood based, assayed control for monitoring performance of analysis for HbA1c.

3. Special condition for use statement(s): None

4. Special instrument Requirements: Beckman Synchron/CX7, Dade Dimension, Bio-Rad Varian/II, Tosoh G7/A1c, Roche Integra

H. Device Description:
A1c-Chex consists of Control materials for verifying performance of analysis procedures for HbA1c. The controls contain human red blood cells and preservative suspension medial packaged in a 15 x 30 mm clear glass vial.

I. Substantial Equivalence Information:

1. Predicate device name(s): Medical Analysis Systems, Inc. Diabetes Control

2. Predicate K number(s): k023307

3. Comparison with predicate:

DEVICE	PREDICATE
The controls contain human red blood cells and preservative suspension media. This control can be used to monitor RBC lysis.	MAS Diabetes Control is a lyophilized product prepared from human whole blood adjusted to specific concentrations of glycolated hemoglobin. MAS Diabetes control does not monitor the RBC lysis in the hemoglobin A1c analytic methods.
A1c-Chex has an open vial stability of 30 days.	MAS Diabetes Control has an open vial stability of 14 days.

J. Standard/Guidance Document Referenced (if applicable) None Referenced

K. Test Principle: N/A

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

    b. *Linearity/assay reportable range:* N/A

    c. *Traceability (controls, calibrators, or method):*

    Each lot is assayed by up to eight different reagents with at least three different methodologies (immunoassays, Ionic Exchange HPLC, Boronate affinity). The abnormal level expected range is derived from the mean of all the values $\pm 2\%$. The normal level expected range is derived from the mean of all the values $\pm 1\%$.

    d. *Detection limit (functional sensitivity:* N/A

    e. *Analytical specificity:* N/A

    f. *Assay cut-off:* N/A

2. Comparison studies:
    a. *Method comparison with predicate device:* NA

    b. *Matrix comparison:* NA

3. <u>Clinical studies:</u>
   a. *Clinical sensitivity:* N/A

   b. *Clinical specificity:* N/A

4. <u>Clinical cut-off:</u> N/A

5. <u>Expected values/Reference range:</u> N/A

M. Conclusion: Based upon the information provided, I recommend that the Streck Laboratories A1c-Chex control system be found substantially equivalent with the predicate device as defined in 21 CFR 862.1660.