

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

A. 510(k) Number:

k042717

B. Purpose for Submission:

Notification of intent to manufacture and market the device: MAS® Diabetes Control and Dade® Diabetes Control Liquid Assayed Diabetes Control Levels 1 and 2

C. Analyte: N/A

D. Type of Test: N/A

E. Applicant:

Medical Analysis Systems, Inc

F. Proprietary and Established Names:

Proprietary - MAS® Diabetes Control and Dade® Diabetes Control Liquid Assayed Diabetes Control Levels 1 and 2
Established - Liquid Assayed Diabetes Control Levels 1 and 2

G. Regulatory Information:

1. Regulation section:

Quality Control Material – 21 CFR 862.1660

2. Classification:

Class I

3. Product Code:

JJX

4. Panel:

75

H. Intended Use:

1. Intended use(s):

Diabetes Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for Hemoglobin A1c and methods listed in the package insert.

2. Indication(s) for use:

Diabetes Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for Hemoglobin A1c and methods listed in the package insert.

3. Special condition for use statement(s):

For Prescription Use

4. Special instrument Requirements: N/A

I. Device Description:

The MAS Diabetes Control Liquid Assayed Diabetes Control Levels 1 and 2, and the Dade Diabetes Control Liquid Assayed Diabetes Control Levels 1 and 2 Diabetes Control are liquid assayed quality control products prepared from human whole blood adjusted to specific concentrations of glycolated hemoglobin. Preservatives and stabilizers are added to maintain product integrity. The human whole blood used as the matrix for the calibrators and controls is tested and shown to be non-reactive for HBsAg, HIV, and anti-HCV using FDA approved methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bioresource Technology Glycosylated Hemoglobin A1C Control Normal and Elevated

2. Predicate K number(s):

k023032

3. Comparison with predicate:

| Item | Device | Predicate |
|------------------|--|---|
| Intended Use | The MAS Diabetes Control Liquid Assayed Diabetes Control Levels 1 and 2, and the Dade Diabetes Control Liquid Assayed Diabetes Control Levels 1 and 2 Diabetes Control are intended for use as assayed quality control materials to monitor the precision of laboratory testing procedures for the analyte and methods listed in the package insert. | Intended for use as an assayed quality control material for monitoring Glycosylated Hemoglobin (A1C) assay procedures |
| Product Code | JJX | GFS |
| Product State | Liquid | Liquid |
| Stability Claims | 2 years unopened at -20°C 12 months unopened at 2 - 8 °C 14 days opened at 2 - 8 °C | 2 years unopened at -20°C 12 months unopened at 2 - 8 °C 14 days opened at 2 - 8 °C |

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

The firm does not reference any Standard or Guidance Documents.

L. Test Principle: N/A

M. 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):*

No traceability was provided. The assigned ranges for these controls are based upon replicate assays of representative samples of the product by participating laboratories in accordance with established protocol. All values have been assigned with instruments and instrument manufacturer's reagents available at the time of assay. Subsequent instrument or reagent modifications may invalidate these assigned ranges.

Real time stability using multiple lots on vials stored at 2 – 8° C for 14 days resulted in no significant change: Hemoglobin A1C Level 1, Fresh 5.63, 14 days 5.67, %Change = 1%; Level 2, Fresh 10.1, 14 days 9.9, % change = -1.0%.

Stress stability using multiple lots on vials stored at 25° C for 8 days resulted in no significant change: Hemoglobin A1C Level 1, Fresh 5.7, 8 days 5.7, %Change = 0%; Level 2, Fresh 10.1, 8 days 9.9, % change = -2.3%.

- 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:* N/A
- 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: N/A

N. Conclusion:

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