

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

**A. 510(k) Number:**

k093724

**B. Purpose for Submission:**

New device

**C. Measurand:**

Control material for Blood Glucose Monitoring Systems

**D. Type of Test:**

Not applicable

**E. Applicant:**

TaiDoc Technology Corporation

**F. Proprietary and Established Names:**

Taidoc Control Solution and FORA Control Solution

**G. Regulatory Information:**

1. Regulation section:

21 CFR §862.1660, Quality Control Material (Assayed and Unassayed)

2. Classification:

Class I, reserved

3. Product code:

JJX - Single (Specified) Analyte Controls (Assayed and Unassayed)

4. Panel:

Clinical Chemistry

## H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The FORA Glucose Control Solution and Taidoc Glucose Control Solution are intended for *in vitro* diagnostic use (i.e. for external use only) to assess the performance of the blood glucose test meters and test strips manufactured by Taidoc Technology Corporation by healthcare professionals and in the home by people with diabetes mellitus.

3. Special conditions for use statement(s):

For *in vitro* diagnostic use

4. Special instrument requirements:

**FORA/Taidoc Low, Normal and High (GOD test strips)**

TD-3213, TD-3215, TD-3216, TD-3217, TD-3260, TD-3261 (k062800)

TD-3223E (k093592)

TD-3224 (k081714)

TD-3260 (k080014)

TD-3250 (k061073/k080014)

TD-3252 (k091555)

TD-3263 (k080014)

TD-4207, TD-4209, TD-4222, TD-4225, TD-4226 (k090185)

TD-4223 E, TD-4223 F, TD-4224 (k072039)

TD-4227 (k090188),

TD-4229 (k072489)

TD-4230, SMS-4230 (070472)

TD-4231 (k063212)

Prodigy Voice (k073118)

TD-4234 (k091898)

TD-4237, AudioCheck (k081609)

TD-4238, TD-4246 (k092902)

SMS-4240 (k080501)

TD-4242 (k093635)

TD-4247 (k081957)

TD-4249, TD-4250 (k083570)

TD-4253, TD-4252, TD-4253, TD-4254 (k092099)

TD-4264, TD-4273, TD-4275 (k093005)

Clever Choice (k093941)

Clever Choice Auto-code (k093506)

D20 (k091814)

G90 (k100405)  
 G30a (k100732)  
 V30 (k093635)  
 V10 (k093035)  
 V20 (k100406)  
 TD-4251 (k092099)  
 G70, G72a, G73 (k093005)  
 G71a (k093712)

**FORA/Taidoc Level 1, Level 2, Level 3 (GDH test strips):**  
 TD-4222, TD-4230, TD-4231, TD-3250C, TD-3260 (k082169),  
 TD-4225 (k051854),

**I. Device Description:**

The Taidoc and FORA Glucose Control solutions are viscosity-adjusted, buffered aqueous control solutions that contain known concentrations of d-glucose. Non-reactive formulation ingredients include: buffers, stabilizer, and preservative. The products are intended for use to verify the performance of the blood glucose meters and test strips manufactured by Taidoc Technology Corporation. There are 2 sets of 3-level quality control materials. The first set (FORA and Taidoc) consists of Low , Normal and High levels, while the second set (Tadoc and FORA) consists of Level 1, Level 2 and Level 3 . The FORA Control Solutions (Low, Normal and High) and Taidoc (Low, Normal and High) are for use with glucose oxidase test strips. The FORA Control Solutions (Level1, Level 2 and Level 3) and Taidoc Control Solutions (Level 1, Level 2 and Level 3) are for use with glucose dehydrogenase test strips.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Taidoc Control solutions

2. Predicate K number(s):

k041107

3. Comparison with predicate:

	<b>Candidate devices:</b>		<b>Predicate Device:</b> <b>FORA Control Solution</b> <b>(k041107)</b>
	<b>FORA/Taidoc</b>	<b>FORA/Taidoc</b>	

	Candidate devices:		Predicate Device: FORA Control Solution (k041107)
	FORA/Taidoc	FORA/Taidoc	
Indications for Use	To check the performance of blood glucose monitoring systems manufactured by Taidoc	Same	Same
Analyte	d-glucose	Same	Same
Matrix	Aqueous	Same	Same
Number of Level(s)	3	3	2
Target Ranges	Low (60 – 80 mg/dL) Normal (100 - 150 mg/dL) High (250-350 mg/dL)	Level 1 (35 – 65 mg/dL) Level 2 (112 – 168 mg/dL) Level 3 (224 – 336 mg/dL)	Normal (100 - 150 mg/dL) High (250-350 mg/dL)

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

None referenced.

**L. Test Principle:**

Not applicable.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable

b. *Linearity/assay reportable range:*

Not applicable

*c. Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability:

The sponsor claims traceability to the NIST Standard Reference Material (SRM) 917A.

Stability:

Stability testing protocols and acceptance criteria were reviewed and found to be acceptable. Stability characteristics of the FORA Control solutions and Taidoc Control solutions were determined under un-opened and opened conditions in real time stability studies. An unopened shelf-life of 2 years (24 months) was demonstrated at the recommended storage temperature (36°F-86°F). Open vial stability of 90 days (3 months) was demonstrated at the recommended storage temperature of 36°F-86°F. The recommendations in the labeling are to store control solutions at room temperature and additional warnings are given to not freeze or refrigerate control solutions.

Value assignment:

Value assignment was established using 25 glucose meters and 25 strips from one test strip lot for each Blood Glucose Monitoring System listed in H.4.7 above. The control range for each control solution is listed on the test strip vial. The final control ranges, printed on the vials, are within +/-20% of the mean value for each control solution tested. The expected results may change with each new lot. However, in the package insert, the user is directed to compare their control result with the range printed on the test strip vial.

*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):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The expected values for each control level are provided on the test strip vial labels and in the package insert for each specific lot.

**N. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**O. Conclusion:**

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