

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

k080283

B. Purpose for Submission:

Modification of a cleared device by changing the appearance and adding Bluetooth capability for transmission to a personal computer or a compatible device validated by the manufacturer.

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Blood Glucose Concentration through a Quantitative Amperometric Assay (Glucose Oxidase)

E. Applicant:

TaiDoc Technology Corporation

F. Proprietary and Established Names:

IDEAL LIFE Gluco-Manager GMM 0001 Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.1345, Glucose Test System
2. Classification:
Class II
3. Product code:
NBW, CGA
4. Panel:
75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):
See Indications for use.
2. Indication(s) for use:
The IDEAL LIFE Gluco-Manager GMM Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus.

The alternative site testing in this system can be used only during steady-state blood glucose conditions.

This system offers Bluetooth wireless communication function which is able to transfer historical data in the memory to other devices, such as PC or a compatible device validated by the manufacturer.

3. Special conditions for use statement(s):
 - Not for neonatal use
 - Not for screening or diagnosis of diabetes mellitus
 - Alternative site testing is for use at times of steady state only
 - Not for patients who are dehydrated, in shock, critically ill, or in a hyperosmolar state
4. Special instrument requirements:
IDEAL LIFE Gluco-Manager GMM 0001 Blood Glucose Monitoring System

I. Device Description:

The IDEAL LIFE Gluco-Manager GMM 0001 Blood Glucose Monitoring System is based on an electrochemical biosensor technology (electrochemical) and the principle of capillary action. Capillary action at the end of the test strip draws the blood into the action chamber and the blood glucose result is displayed in 7 seconds. The control solutions available are used to test the performance of the device and were cleared under k012430.

J. Substantial Equivalence Information:

1. Predicate device name(s):
ACHTUNG TD-4207 Blood Glucose Monitoring System
2. Predicate 510(k) number(s):
k061181
3. Comparison with predicate:

| Similarities | | |
|---------------------|-------------------------------------|-------------------------------------|
| Item | Device | Predicate |
| Detection Method | Amperometry | Amperometry |
| Enzyme | Glucose Oxidase | Glucose Oxidase |
| Test Range | 20 – 600 mg/dL | 20 – 600 mg/dL |
| Test Time | 7 seconds | 7 seconds |
| Volume Required | 0.7 µL | 0.7 µL |
| Meter Coding | Test Strip Insertion/Code Selection | Test Strip Insertion/Code Selection |

| Differences | | |
|----------------------------|--------|-----------|
| Item | Device | Predicate |
| Wireless Data Transmission | Yes | No |

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

- ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
- CLSI EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices
- CLSI EP9-A: Method Comparison and Bias Estimation Using Patient Samples

L. Test Principle:

Glucose measurement is based on electrical potential caused by the reaction of glucose with

the reagents contained on the strip's electrodes. The glucose in the sample is oxidized by the enzyme glucose oxidase, and the current resulting from this enzymatic reaction is measured and converted to glucose concentration by the meter. The magnitude of the current is proportional to the concentration of glucose in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

For performance of the glucose meter and test strips, see k061181. The performance from k061181 is provided below:

The sponsor evaluated the precision of the device using replicate measurements of glucose control solutions and anticoagulated venous whole blood. In order to determine that the change in sample volume does not affect precision, the sponsor tested four volume levels (0.5, 0.6, 0.7, and 0.8 μ L) of venous whole blood collected from 10 volunteers. The ten samples were pooled together, depleted of glucose, and then separated into three groups. Each group was spiked with a dextrose solution to within the desired concentration range: low 60-92 mg/dL, normal 109-165 mg/dL and high 259-389 mg/dL. Different testing volumes (0.5uL, 0.6uL, 0.7uL and 0.8 uL) of each sample were evaluated for repeatability. Since the volume claimed is 0.7 μ L, only the 0.7 μ L data is presented below.

| Patient | Low Control Level (60-92 mg/dL) | | | Mid Control Level (109-165 mg/dL) | | | High Control Level (259-389 mg/mL) | | |
|-------------|---------------------------------|-------|-------|-----------------------------------|-------|-------|------------------------------------|-------|-------|
| | Lot 1 | Lot 2 | Lot 3 | Lot 1 | Lot 2 | Lot 3 | Lot 1 | Lot 2 | Lot 3 |
| 1 | 68 | 68 | 72 | 139 | 139 | 144 | 309 | 309 | 300 |
| 2 | 68 | 68 | 65 | 132 | 132 | 141 | 310 | 310 | 297 |
| 3 | 70 | 70 | 71 | 130 | 130 | 133 | 314 | 314 | 307 |
| 4 | 68 | 68 | 71 | 136 | 136 | 137 | 308 | 308 | 300 |
| 5 | 72 | 72 | 70 | 133 | 133 | 141 | 311 | 311 | 297 |
| 6 | 72 | 72 | 72 | 133 | 133 | 134 | 312 | 312 | 313 |
| 7 | 70 | 70 | 74 | 137 | 137 | 131 | 306 | 306 | 305 |
| 8 | 69 | 69 | 71 | 135 | 135 | 134 | 313 | 313 | 302 |
| 9 | 65 | 65 | 69 | 134 | 134 | 141 | 310 | 310 | 301 |
| 10 | 64 | 64 | 74 | 137 | 137 | 145 | 305 | 305 | 305 |
| Total CV(%) | 3.98 | | | 2.85 | | | 1.60 | | |

b. *Linearity/assay reportable range:*

The linearity of the device was originally demonstrated in k041107. The sponsor verified accuracy of the device over the reportable range (20 – 600 mg/dL) against a standard detection method (see Method Comparison below).

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

The controls supplied with this device were previously cleared under k012430. The

sponsor has shown traceability of the meter to a laboratory analyzer. The sponsor has described their strip stability testing protocol and acceptance criteria which were found to be acceptable.

d. Detection limit:

The measuring range of the IDEAL LIFE Gluco-Manager GMM 0001 Blood Glucose Monitoring System is 20 - 600 mg/dL. This range was verified by the linearity study (referenced from k041107).

e. Analytical specificity:

The specificity of the device was assessed in k041107. Given that the fundamental technology has not changed from k041107, the sponsor claims that elevated blood triglycerides and the following substances do not affect results: acetaminophen, dopa, methyldopa, L-dopa and tolbutamide occurring in expected blood concentrations. Due to the change in read time of the glucose oxidase reaction, the sponsor provided studies of reducing substances along with an altitude study for the new strips. Reducing substances such as uric acid and ascorbic acid occurring in expected blood concentrations (0-3 mg/dL and 5-20 mg/dL respectively) were shown not interfere with glucose measurements. The altitude study also showed that the percentage of mean difference between strips is within the acceptable range (as defined by ISO 15197: within ± 15 mg/dL when glucose concentration < 75 mg/dL and within $\pm 20\%$ when glucose concentration ≥ 75 mg/dL) indicating that the new test strips are equivalent to the predicate strips at the same altitude (up to 10,744 feet).

f. Assay cut-off:

Not Applicable.

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor demonstrated that the GMM 0001 Blood Glucose Monitoring System for finger stick is equivalent to a standard method (YSI-2300) by having 121 patients for the standard method compared to finger stick

The studies are summarized below:

| | YSI vs. Finger |
|-----------|-------------------|
| N | 121 |
| Slope | 0.9609 |
| Intercept | 5.4984 |
| r | 0.9917 |

Finger versus YSI and each site met the ISO 15197 standard of ninety-five percent (95 %) of the individual glucose results falling within ± 15 mg/dL of the results of the comparator method at glucose concentrations for samples < 75 mg/dL and within ± 20

% at glucose concentrations ≥ 75 mg/dL. The samples that met the ISO 15197 requirement are summarized in the table below:

| | |
|---|---------------------|
| Patient | Fingerstick vs. YSI |
| Samples < 75 mg/dL within ± 15 mg/dL YSI | 37/38 (97%) |
| Samples ≥ 75 mg/dL within $\pm 20\%$ YSI | 80/83 (96%) |
| Total | 117/121 (97%) |

For performance of the glucose meter and test strips, see also k061181. The performance from k061181 (with alternate site testing) is provided below:

The sponsor demonstrated that the ACHTUNG TD-4207 Blood Glucose Monitoring System for finger stick is equivalent to a standard method (YSI-2300) and can be used on alternate sites (specifically the capillary blood from finger compared to the palm, forearm, upper arm, calf, and thigh) by having 120 patients for the standard method compared to finger stick and 100 patients for each alternate site test the meter. For the finger stick against the standard method, samples ranged as follows: 10% of samples were 20-50 mg/dL, 35% of samples were 51-110 mg/dL, 30% of samples were 111-150 mg/dL, 10% of samples were 151-250 mg/dL, 10% of samples were 251-400 mg/dL, and 5% of samples were 401-600 mg/dL. For the AST sites, the samples ranged as follows: 40% of samples were 51-110 mg/dL, 30% of samples were 111-150 mg/dL, 20% of samples were 151-250 mg/dL, and 10% of samples were 251-400 mg/dL. All patients blood glucose levels were in a steady state for these studies. The studies are summarized below:

| | YSI vs. Finger | Finger vs. Palm | Finger vs. Forearm | Finger vs. Upper arm | Finger vs. Calf | Finger vs. Thigh |
|-----------|----------------|-----------------|--------------------|----------------------|-----------------|------------------|
| N | 120 | 100 | 100 | 100 | 100 | 100 |
| Slope | 1.0052 | 1.0057 | 0.8716 | 0.9102 | 0.9173 | 0.9842 |
| Intercept | 1.7264 | 1.8744 | 9.1884 | 6.2178 | 5.3413 | 0.7822 |
| r | 0.9948 | 0.9889 | 0.9839 | 0.9822 | 0.9822 | 0.9805 |

Finger versus YSI and each site met the ISO 15197 standard of ninety-five percent (95 %) of the individual glucose results falling within ± 15 mg/dL of the results of the comparator method at glucose concentrations for samples <75 mg/dL and within ± 20 % at glucose concentrations ≥ 75 mg/dL. The samples that met the ISO 15197 requirement are summarized in the table below:

| Site | Finger | Palm | Forearm | Upper arm | Calf | Thigh |
|-------------------------------------|----------------|--------------|----------------|--------------|--------------|--------------|
| N | 120 | 100 | 100 | 100 | 100 | 100 |
| Percentage That Met ISO Requirement | 100% (120/120) | 99% (99/100) | 100% (100/100) | 98% (98/100) | 98% (98/100) | 98% (98/100) |

The sponsor also has labeling indicating the conditions under which AST can be used and when AST should not be used.

b. Matrix comparison:

Not applicable. Capillary whole blood is the only indicated matrix.

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):

The sponsor provided a readability study that indicated that the user manual, test strip labeling, and control solution labeling is at an 8th grade reading level or below.

4. Clinical cut-off:

Not Applicable.

5. Expected values/Reference range:

The sponsor included the following expected values for normal glucose levels in their strip labeling:

Fasting and before meals - 70-110 mg/dL (3.9-6.1 mmol/L)¹

Hours after meals - Less than 140 mg/dL (7.8mmol/L)²

¹Sacks, DB in "Carbohydrates", Burtis, CA, Ashwood, ER(ed), Tietz Textbook of Clinical Chemistry, Philadelphia, WB Saunders Company, 1999.

²ADA Clinical Practice Recommendations 2003.

N. Instrument Name:

IDEAL LIFE Gluco-Manager GMM 0001 Blood Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for additional readings. The IDEAL LIFE Gluco-Manager GMM 0001 Blood Glucose Monitoring System is capable of data transmission to a PC or a compatible device validated by the manufacturer.

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes X or No

3. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly

to the test strip as they are collected.

4. Specimen Sampling and Handling:

This device is intended to be used with capillary whole blood from the finger, palm, forearm, upper arm, calf, and thigh only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

A code number is provided with each batch of test strips to calibrate the meter for that batch. The code number must be entered into the meter to match the number found on the test strip vial. No further calibrations are required of the user.

6. Quality Control:

The sponsor is providing a low, medium, high glucose control solutions with this device. When a test strip is inserted into the meter, the control mode can be activated. This prevents control results from being stored in the internal memory. An acceptable range for each control level is printed on the test strip vial label.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:

None.

Q. Proposed Labeling:

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

R. Conclusion:

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