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

A. 510(k) Number:
k072441

B. Purpose for Submission:
Modification to a cleared device: Addition of alternate sites (palm and forearm) and change in coding from a code key to manual entry of the calibration code.

C. Measurand:
Whole blood glucose

D. Type of Test:
Blood Glucose Concentration through a Quantitative Amperometric Assay (Glucose Oxidase)

E. Applicant:
Tyson Bioresearch, Inc.

F. Proprietary and Established Names:
EZ Scan Plus 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 below.

2. Indication(s) for use:
   The EZ Scan Plus Glucose Test Strips are used with the EZ Scan Plus Blood Glucose Meter for quantitatively measuring glucose (glucose) in fresh capillary whole blood drawn from the fingertip and the alternate sites: palm and forearm. The EZ Scan Plus Test Strips are for testing outside the body (in vitro diagnostic use). The EZ Scan Plus Blood Glucose Monitoring System is intended for use at home (over the counter [OTC]) by persons with diabetes, or in clinical setting by healthcare professionals as an aid in monitoring the effectiveness of diabetes control.

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:
   EZ Scan Plus Blood Glucose Monitoring System

I. Device Description:

The EZ Scan Plus 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 10 seconds. The control solutions available are used to test the performance of the device.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Tyson Bioresearch, Inc. EZ Smart – 168 Blood Glucose Monitoring System
2. Predicate 510(k) number(s):
   k052818
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
Volume Required	1.5 μL	1.5 μL
Hematocrit Range	35-55%	35-55%
Test Time	10 seconds	10 seconds

Differences		
Item	Device	Predicate
Alternate Site Testing	Yes	No
Meter Coding	Test Strip Insertion/Code Selection	Glucode Chip

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.
- EP7-P NCCLS: Interference Testing in Clinical Chemistry; Approved Guideline.

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. <u>Analytical performance:</u>
     a. *Precision/Reproducibility:*
        The sponsor evaluated the within run and between run precision of the device using 50 replicate measurements of 5 concentrations of glucose-adjusted venous whole blood with 3 strip lots. Results are summarized below.

Within-Run Precision					
Average glucose concentration (mg/dL)	45.8	81.2	128	215	346
SD (mg/dL)	3.0	3.6	4.8	6.0	6.6
CV (%)	6.6	4.4	3.8	2.8	1.9
Between Run Precision					
Average glucose concentration (mg/dL)	46.5	77.2	130.4	223.9	349.6
SD (mg/dL)	3.4	3.7	5.5	6.6	6.8
CV (%)	7.3	4.8	4.2	3.0	1.9

     b. *Linearity/assay reportable range:*
        To establish the linearity of the system through the range of 20 to 600 mg/dL, glucose adjusted whole blood samples (actual range tested was 25 to 572 mg/dL) were compared to YSI 2300 using 50 replicate measurements of 5 concentrations of glucose-adjusted venous whole blood with 3 strip lots Linear regression yields the following statistics:

	Slope	y-intercept	r^2
Strip Lot 1	0.998	0.458	0.999
Strip Lot 2	0.999	-0.120	0.999
Strip Lot 3	1.007	-0.500	0.999

     The sponsor claims 20 mg/dL as the lowest detectable limit in the labeling.

     c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
        The controls were evaluated in the predicate device (k052818). The evaluation of the controls in that submission is described below:

        Traceability has been referenced by the manufacturer to ISO 17511.

        The three control solutions consist of buffered aqueous solutions of D (+)-glucose containing stabilizers, preservatives, and other non-reactive ingredients. Lot-specific ranges are printed on the EZ Smart-168 Test Strip bottle label. The control values are

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assigned by repeat testing. Mean values are obtained and ranges are assigned based upon the mean value ± a pre-determined value for each control concentration.

Closed Vial Stability of Control Solution: The sponsor assessed control solution stability using accelerated and real time aging studies. Five EZ Smart-168 meters and the YSI 2300 Stat Plus analyzer were used during the testing procedure. The shelf life stability claim is 24 months.

Opened Vial Stability of Control Solution: The sponsor conducted open vial stability studies of control solutions (Level 1, 2, and 3) that were stored at room temperature (15°-28° C). Samples were tested every week for 4 consecutive weeks, then every other week for the second month, and every month for the 3 rd to 6th months. Five EZ Smart-168 glucose meters and the YSI 2300 STAT PLUS were used during the testing procedure. The open vial stability claim of the control solutions is 3 months after opening.

The device is traceable to a laboratory analyzer which is calibrated to a glucose standard (NIST SRM 965a).

Stability characteristics of the control solutions were determined using real time aging studies. The open vial storage stability at room temperature was determined to be 18 months and unopened vial stability was determined to be 24 months.

The expected ranges of the glucose control solutions were established by repeat testing (10 times) on two meters using one lot of strips for both glucose levels.

d. *Detection limit:*
The measuring range of the system is 20 - 600 mg/dL as established in k052818. This range was verified by the linearity study (above section M.1.b.).

e. *Analytical specificity:*
The sponsor tested the following substances for interference according to NCCLS EP7-P. Blood samples were drawn from healthy volunteers, mixed, and the interfering chemicals or control samples (saline) were added. Parallel testing was used to compare glucose measurements in the presence and absence of drugs using heparinized venous blood from healthy volunteers. The low and high venous blood glucose concentrations in this study were 61 and 200 mg/dL respectively. For each drug level, one control sample (no interferant) and four test samples with serial dilution concentration were prepared. Control samples were measured by each device to serve as the reference measurement for each glucose test. Each sample was measured in duplicate (glucose concentration 61 mg/dL and 200 mg/dL). Results were averaged for the control samples (n=5) and for the four parallel test samples (n=5). Results are summarized below:

Interferent	Therapeutic Test Level (mg/dL)	High Test Level (mg/dL)	Highest Level Of No Interference (mg/dL)
Acetaminophen	2	4	3
Alcohol	-	3500	3500
Ascorbic acid	2	15	7.5
Bilirubin	1.2	20	20
Caffeine	-	100	100
Cholesterol	30	500	500
Creatinine	1.5	30	30
EDTA	-	4	4
Ibuprofen	4.2	40	40
L-Dopa	0.3	2	1
Salicylate	30	125	125
Sodium Fluoride	-	500	500
Tetracycline	0.4	4	4
Tolazamide	2.5	5	3.75
Tolbutamide	10	100	100
Triglyceride	190	2000	2000
Urea	-	5000	5000
Uric acid	7.7	20	20

An altitude study was performed with venous blood spiked with 5 different concentrations of glucose spanning 70 to 400 mg/dL, and capillary whole blood from volunteers whose blood glucose ranged from 74 to 99 mg/dL. The altitude study was performed at 164, 7545, and 9875 feet and demonstrated that both the venous and capillary blood tests met the sponsor's acceptance criteria of ±15% at altitudes of 7545 feet and below..

To test the effect of hematocrit on the device accuracy, blood adjusted to hematocrit levels of 30%, 35%, 40%, 45%, 50%, 55%, and 60% at glucose concentrations of 48.6, 86.5, 148, 236, 383 mg/dL were tested a total of 6 times, averaged and compared to the YSI result. The study demonstrated a bias of $\leq$ 10% when samples within the claimed hematocrit range of 35% to 55% were compared to YSI.

f. *Assay cut-off*:
Not Applicable.

2. Comparison studies:
a. *Method comparison with predicate device:*
A consumer study on samples ranging from 56.7 to 471 mg/dL was performed with 121 lay-users and a technician. An additional 17 samples were contrived to produce low and high sample values, ranging from 24.2 to 54.3 mg/dL and 487 to 581 mg/dL. The labeling provided to the users was in English only. Each participant performed their own fingerstick and tested their blood using only the instructions in the user's manual, then a technician performed a second fingerstick using the same meter. An

alternate site study on samples from 2 palm sites, the forearm and the finger were also conducted by the same lay users and technician. This study used uncontrived samples only. Not enough blood was obtained for 2 palm samples (leaving 119 samples tested) and 5 forearm samples (leaving 116 samples tested). Results are summarized below:

Patient	Fingerstick vs. YSI	Thenar Palm vs. Patient FingerStick	Hypothenar Palm vs. Patient FingerStick	Forearm vs. Patient FingerStick
Samples < 75 mg/dL within ±15 mg/dL YSI	12/12 (100%)	6/6 (100%)	6/6 (100%)	12/12 (100%)
Samples ≥ 75 mg/dL within ± 20% YSI	108/109 (99%)	43/44 (98%)	63/63 (100%)	103/104 (99%)
Total	120/121 (99%)	49/50 (98%)	69/69 (100%)	115/116 (99%)

Technician	Fingerstick vs. YSI
Samples < 75 mg/dL within ±15 mg/dL YSI	23/23 (100%)
Samples ≥ 75 mg/dL within ± 20% YSI	115/115 (100%)
Total	138/138 (100%)

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:

   70-110 mg/dL fasting[1]

Less than 120 mg/dL one or two hours after meals[2]

1. Burtis CA Ashwood ER, eds.: Tietz Textbook of Clinical Chemistry. 2nd Edition. W.B. Saunders. Philedelphia. 1994. p. 2190.
2. Krall, L.P. and Beaser, R.S.: Joslin Diabetes Manual. Philadelphia: Lea and Febiger (1989), 138.

N. Instrument Name:
EZ Scan Plus 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.
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, or forearm 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 is associated with the meter by inserting a test strip and entering the code number to match that found on the test strip bottle. No further calibrations are required of the user.
6. Quality Control:
   The sponsor has three levels of controls available for this meter with one level coming with the kit and the other two levels being available through the distributor. When a test strip is inserted into the meter, a control can be run. An acceptable range for each control level is printed on the test strip vial label. The user is referred to a troubleshooting section of the owner's manual to identify possible reasons control results may fall outside these ranges.

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.