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

A. 510(k) Number:

k170079

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose from the fingertips, forearm, and palm

D. Type of Test:

Quantitative amperometric assay (FAD-glucose dehydrogenase)

E. Applicant:

Tyson Bioresearch, Inc.

F. Proprietary and Established Names:

Tyson Bio HT100 Blood Glucose Monitoring System
Tyson Bio HT100-B 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- system, test, blood glucose, over the counter

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use below.

2. Indication(s) for use:

   The Tyson Bio HT100 Blood Glucose Monitoring System:

   The Tyson Bio HT100 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alterative site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro diagnostic use). It is intended for self-testing by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis of or screening for diabetes or for neonatal use.

   The Tyson Bio HT100 Blood Glucose Monitoring System is comprised of the Tyson Bio HT100 Blood Glucose Meter and Tyson Bio HT100 Blood Glucose Test Strip.

   The Tyson Bio HT100-B Blood Glucose Monitoring System:

   The Tyson Bio HT100 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alterative site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro diagnostic use). It is intended for self-testing by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis of or screening for diabetes or for neonatal use.

   The Tyson Bio HT100 Blood Glucose Monitoring System is comprised of the Tyson Bio HT100 Blood Glucose Meter and Tyson Bio HT100 Blood Glucose Test Strip.

3. Special conditions for use statement(s):

   Special conditions for use statement(s) for Tyson Bio HT100 Blood Glucose Monitoring System and Tyson Bio HT100-B Blood Glucose Monitoring System
   - Use only capillary whole blood from finger, palm, and forearm
   - Do not use for testing neonatal blood
   - Altitude higher than 10745 feet may cause inaccurate results.

- Severe dehydration and excessive water loss may lead to inaccurate blood glucose test results. Consult your physician immediately if you believe you are suffering from severe dehydration.
- For single-patient use only and should not be shared.
- Should not be used to test critically ill patients
- Inaccurate results may occur in severely hypotensive individuals or patients in shock
- Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis
- For in vitro diagnostics use only
- For over-the counter use
- Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly)
- Alternative site measurements should never be used to calibrate continuous glucose monitoring (CGMs)
- Alternative site measurements should never be used for insulin dosing calculation
- This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

4. Special instrument requirements:

   Tyson Bio HT100 Blood Glucose Meter
   Tyson Bio HT100-B Blood Glucose Meter

I. Device Description:

The Tyson Bio HT100 Blood Glucose Monitoring System consists of the Tyson Bio HT100 Blood Glucose Meter, the Tyson Bio HT100 Blood Glucose Test Strips, and the Tyson Bio HT100 Control Solution.

The Tyson Bio HT100-B Blood Glucose Monitoring System consists of the Tyson Bio HT100-B Blood Glucose Meter, the Tyson Bio HT100-B Blood Glucose Test Strips and the Tyson Bio HT100-B Control Solution. The Tyson Bio HT100-B Blood Glucose Monitoring System has Bluetooth transmission capability and the results from the Tyson Bio HT100-B Blood Glucose meter can be transmitted to a Bluetooth-capable cellphone.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   ACCU-CHEK Performa Blood Glucose Monitoring System

2. Predicate 510(k) number(s):

   k133741

3. Comparison with predicate:

Similarities			
Item	Predicate Device (k133741)	Candidate Device (k170079)	
	ACCU-CHEK Performa Blood Glucose Monitoring System	Tyson Bio HT100 Blood Glucose Monitoring System	Tyson Bio HT100-B Blood Glucose Monitoring System
Indications for Use	Intended for the quantitative measurement of glucose in fresh capillary whole blood samples	Same	Same
Test Principle	Amperometry	Same	Same
Methodology	Electrochemical biosensor with Glucose Dehydrogenase (FAD)	Same	Same
Hematocrit	10%-65%	Same	Same
Measuring Range	20-600 mg/dL	Same	Same
Memory capacity	500 results with time and date	Same	Same

Differences			
Item	Predicate Device (k133741)	Candidate Device (k170079)	
	ACCU-CHEK Performa Blood Glucose Monitoring System	Tyson Bio HT100 Blood Glucose Monitoring System	Tyson Bio HT100-B Blood Glucose Monitoring System
Sample Type	Capillary whole blood samples drawn from the fingertips	Capillary whole blood samples drawn from the fingertips, forearm, or palm	Capillary whole blood samples drawn from the fingertips, forearm, or palm
Battery Type	One CR2032	Two AAA batteries	Two AAA batteries
Sample volume	0.6uL	0.7uL	0.7uL
Operating Temperature Range	16 to 35 °C (61-95°F)	10 to 40 °C (50-104°F)	10 to 40 °C (50-104°F)
Operating Humidity Range	10-80%	10-90%	10-90%
Coding	Code key required	Auto coding	Auto coding
Bluetooth	none	none	Bluetooth transmission capability to a Bluetooth-capable cellphone

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

CLSI EP07-A2, "Interference Testing in Clinical Chemistry"; Approved Guideline

L. Test Principle:

Quantitative measurement of glucose within whole blood using the Tyson Bio HT100/ Tyson Bio HT100-B Blood Glucose Monitoring Systems, an amperometric biosensor, begins with a small drop of blood. This blood sample is then placed onto the Tyson Bio HT100 Test Strip where it is diffused and solvated into the reagent layer, which contains glucose dehydrogenase, potassium ferricyanide and nonreactive ingredients. Glucose in the sample reacts with glucose dehydrogenase and potassium ferricyanide. Electrons are generated producing a current, which is proportional to the glucose in the sample. This current is then measured and correlated to the glucose concentration within the whole blood sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

The two systems in this submission are identical except for the presence or absence of blue tooth functionality and the name; therefore, performance data provided in this section using the Tyson Bio HT100 Blood Glucose Monitoring System is applicable to both systems.

a. Precision/Reproducibility:

The sponsor performed repeatability precision studies (within-run precision) using pooled venous whole blood samples spiked with glucose to eight glucose - concentration ranges (20-29 mg/dL, 30-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, 251-400 mg/dL, 401-500 mg/dL, and 501-600 mg/dL). Each glucose sample was measured in replicates of 10 using 3 test strip lots and 10 meters for a total of 300 tests for each glucose level. Results are summarized below:

Glucose Concentration (mg/dL)	Strip lot	n	Mean (mg/dL)	SD (mg/dL)	% CV
20-29	1	100	22.0	1.9	8.6
	2	100	23.3	1.9	8.2
	3	100	23.4	1.8	7.7
30-50	1	100	43.9	3.9	8.9
	2	100	44.3	3.9	8.9
	3	100	45.5	3.4	7.5
51-110	1	100	85.0	3.0	3.6
	2	100	84.8	2.9	3.4
	3	100	86.7	3.1	3.6
111-150	1	100	146.7	3.9	2.7
	2	100	145.0	3.8	2.6
	3	100	145.3	3.8	2.6
151-250	1	100	217.2	4.2	1.9
	2	100	219.3	5.0	2.3
	3	100	221.3	5.6	2.5
251-400	1	100	330.0	6.9	2.1
	2	100	341.0	5.8	1.7
	3	100	341.2	6.8	2.0
401-500	1	100	449.5	6.8	1.5
	2	100	449.8	6.9	1.5
	3	100	449.6	8.0	1.8
501-600	1	100	549.3	10.8	2.0
	2	100	552.7	13.8	2.5
	3	100	551.1	9.7	1.8

Intermediate (between day) precision was evaluated using 3 lots of test strips and 10 meters. Glucose control solutions in three concentration ranges were used (60-80 mg/dL, 96-114 mg/dL and 280-420 mg/dL). Each sample was tested over 10 days with each meter, for each test strip lot, resulting in a total of 100 measurements per lot and 300 measurements per glucose level. Results are summarized below:

Glucose Concentration (mg/dL)	Strip lot	n	Mean (mg/dL)	SD (mg/dL)	% CV
30-50	1	100	47.3	3.0	6.4
	2	100	48.2	3.1	6.5
	3	100	49.8	3.2	6.5
96-144	1	100	130.3	4.9	3.8
	2	100	131.2	4.8	3.7
	3	100	130.5	3.9	3.0
280-420	1	100	345.7	10.7	3.1
	2	100	347.5	10.2	2.9
	3	100	342.1	10.3	3.0

b. *Linearity/assay reportable range:*

Linearity testing was performed using venous whole blood adjusted to 12 different glucose concentrations ranging from 22.8 to 639.4 mg/dL (22.8 mg/dL; 52.9 mg/dL; 81.1 mg/dL; 120.6 mg/dL; 183.1 mg/dL; 255.5 mg/dL; 326.3 mg/dL; 404.3 mg/dL; 466.3mg/dL; 546.5 mg/dL; 586.8 mg/dL; 639.4 mg/dL). Each sample was measured in replicates of 10 with 3 test strip lots and 30 Tyson Bio HT100 blood glucose meters. The values were compared to a laboratory comparator method (YSI 2300 analyzer). The evaluation yielded the following regression analysis:

Lot	Slope	y-intercept	R^2
1	0.9996	4.5779	0.9968
2	0.9955	4.5691	0.9973
3	0.9930	4.6833	0.9961

The results of the study support the claimed glucose measurement range of 20 to 600 mg/dL. If a sample result is less than 20 mg/dL the result is flagged by the meter as "LO" and if a sample result exceeds 600 mg/dL the result is flagged by the meter as "HI". The 'HI/LO' error message feature was validated to demonstrate that the feature functions as intended.

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

Traceability:
The Tyson Bio HT100 Blood Glucose Monitoring System and the Tyson Bio HT100-B Blood Glucose Monitoring System are traceable to a certified glucose reference material (NIST 965b).

Test Strip Stability:

Test strip open vial and closed vial stability was assessed in real-time studies and is ongoing. The testing protocols and acceptance criteria were reviewed and found to be acceptable. The manufacturer claims vial shelf life stability of 1 month and open-vial stability of 1month when stored at 39.2 to 86°F (4-30°C) and relative humidity (RH) of 10-90%. The labeling states: Do not freeze.

d. *Detection limit:*

The reportable range is 20-600 mg/dL. This range was verified by the linearity study (M.1.b above).

e. *Analytical specificity:*

Interference studies were performed by spiking endogenous and exogenous substances into venous whole blood. Each potential interferent was tested at 3 glucose levels (50-100 70 mg/dL, 110-140 mg/dL and 250-350 mg/dL as measured on the YSI 2300 Analyzer) using 3 test strip lots measuring each sample in replicates. The % difference between the test sample and the control sample was calculated. The substances tested and the highest concentrations tested with no significant interference (defined by the sponsor as ≤ 10% bias) are summarized in the table below:

Interference substance	Highest tested concentration with no significant interference
Acetaminophen	4.25 mg/dL
Ascorbate(Ascorbic acid)	3 mg/dL
Bilirubin	25 mg/dL
Cholesterol	1200 mg/dL
Creatinine	10 mg/dL
Dopamine	2 mg/dL
Galactose	500 mg/dL
Gentisic acid	2.5 mg/dL

Interference substance	Highest tested concentration with no significant interference
Glutathione	3.07 mg/dL
Haemoglobin-HUMAN	3000 mg/dL
Heparin	5 IU/mL
Hydrogenated starch hydrolysates (HSH)	0.09 mg/dL
Ibuprofen	50 mg/dL
Icodextrin	750 mg/dL
Isomalt	0.09 mg/dL
Lactitol	0.09 mg/dL
L -DOPA(L-3-4-dihydroxyphenylalanine)	0.5 mg/dL
Maltose	2575 mg/dL
Maltitol	0.09 mg/dL
Mannitol	0.09 mg/dL
Methyldopa	2.5 mg/dL
Pralidoxime iodide (PAM)	5 mg/dL
Salicylate	50 mg/dL
Sodium Carbonate	37.5 mEq/L
Sorbitol	0.09 mg/dL
Tolbutamide	100 mg/dL
Tolazamide	6 mg/dL
Triglycerides	2000 mg/dL
Uric acid	10.0 mg/dL
Xylose	5 mg/dL
Xylitol	0.09 mg/dL

The sponsor included the following information in their labeling:

If you have certain conditions that may cause your blood level of uric acid to rise, such as gout or kidney disease (>10 mg/dL uric acid) then your blood glucose results may be

inaccurate. If you are unsure, then ask your health care professional.

Acetaminophen interferes with this meter. If you are taking acetaminophen containing drugs (Tylenol and other medicines containing acetaminophen) you should not use this meter.

If you are taking Vitamin C (ascorbic acid, blood concentrations >3 mg/dL) at doses higher than recommended, it may interfere with your glucose meter and cause you to get inaccurate results with this system.

Do not use this system during or shortly after receiving xylose absorption therapy; xylose may case inaccurate blood glucose results

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

See section M.2.c. below for the user performance study.

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):

User Performance Studies:
To assess the performance of the Tyson Bio HT100 Blood Glucose Monitoring System in the hands of the intended users, a study was performed at one clinical site using three test strip lots with 121 untrained lay user participants that obtained their own fingerstick, palm and forearm samples. Each subject performed testing on their own sample and results were compared to those obtained by a health care professional on the YSI 2300. The range of glucose values for the samples as measured by YSI was 35 to 348 mg/dL. The results relative to the YSI are summarized below:

Summary of Fingertip vs. YSI

Accuracy for blood glucose levels <75 mg/dL			
Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL	
4/4 (100%)	4/4 (100%)	4/4 (100%)	
Accuracy for blood glucose levels ≥75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15 %	Within ± 20%
96/117 (82%)	116/117 (99%)	117/117 (100%)	117/117 (100%)

Summary of Palm vs. YSI

Accuracy for blood glucose levels <75mg/dL			
Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL	
3/4 (75%)	4/4 (100%)	4/4 (100%)	
Accuracy for blood glucose levels ≥75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15 %	Within ± 20%
88/117 (75%)	114/117 (97%)	117/117 (100%)	117/117 (100%)

Summary of Forearm vs. YSI

Accuracy for blood glucose levels <75mg/dL			
Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL	
3/4 (75%)	4/4 (100%)	4/4 (100%)	
Accuracy for blood glucose levels ≥75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15 %	Within ± 20%
79/117 (68%)	115/117 (98%)	117/117 (100%)	117/117 (100%)

Linear Regression:

Site	Slope	Intercept	R^2	N
Fingertip	0.9772	1.0513	0.9935	121
Palm	0.9913	0.0089	0.9921	121
Forearm	0.9691	3.0295	0.987	121

Prior to the lay-user study the readability of the labeling (user manual, test strip package insert and quick reference guide) was assessed using a Flesch-Kincaid analysis and was found to be written at the 8th grade level.

During the lay user study the participants were asked to complete a questionnaire to evaluate the usability of the use of the device and the clarity of user manual. Overall, the users indicated that they could successfully conduct the test.

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

   The labeling includes the following expected glucose values for people without diabetes:
   Before a meal (fasting): <100 mg/dL
   2 h after a meal: < 140mg/dL

   These ranges were cited from the American Diabetes Association, Classification and Diagnosis of Diabetes, 2017. Diabetes Care 40 (Suppl. 1):S11-S24

N. Instrument Name:

Tyson Bio HT100 Blood Glucose Meter
Tyson Bio HT100-B Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ___X_____ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes ___X_____ or No _____

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 the Tyson Bio HT100 Blood Glucose Meter and the Tyson Bio HT100-B Blood Glucose Meter. As the blood sample is collected from the fingertip, palm or forearm the user directly applies the blood sample to the test strip.

4. Specimen Sampling and Handling:

   Tyson Bio HT100 Blood Glucose Meter and Tyson Bio HT100-B Blood Glucose Meter is intended to be used with capillary whole blood from the fingertip, palm and forearm which can be applied directly to the test strip by capillary action.

5. Calibration:

   There is no calibration required by the user for the Tyson Bio HT100 Blood Glucose Meter and the Tyson Bio HT100-B Blood Glucose Meter. The meters are automatically coded.

6. Quality Control:

   Three levels of controls are available for use with this meter. The control solutions are sold separately. The control solution range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges. The Tyson Bio HT100/HT100-B Blood Glucose meters may be set in a Control Solution test mode by pressing a button; the control results will not be included in any day average calculation when the meter is set in the Control Solution test mode.

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

1. Hematocrit
   The effect of different hematocrit levels on the Tyson Bio HT100 Blood Glucose Monitoring System was evaluated using venous whole blood samples with hematocrit levels of 9-71% (9, 14, 19, 25, 30, 35, 40, 45, 50, 55, 61, 66 and 71%) at 5 concentrations of glucose (27, 64, 134, 224 and 375 mg/dL). Three test strips lots were evaluated with 10 meters. Each sample was tested in replicates for each hematocrit level and glucose levels. For each blood sample, individual glucose readings taken on the Tyson Bio HT100 glucose meter were compared to YSI comparator values to calculate the bias. The % bias of the Tyson Bio HT100 Blood Glucose meter results relative to YSI demonstrated adequate performance to support the claimed hematocrit range of 10-65%. The meter has an Hct H and Hct L feature that was validated to demonstrate that the feature functions as intended.

2. Altitude Testing
   To evaluate the effects of altitude on the Tyson Bio HT100 Blood Glucose Monitoring System, venous blood samples were altered to 9 glucose concentrations intervals (47-53, 75-85, 110-120, 175-195, 245-265, 315-335, 380-410, 450-480, and 520-555 mg/dL) and tested at 164, 5719 and 10745 feet above sea level. Results obtained were compared with those obtained with the comparator method (YSI). The results demonstrate acceptable bias to the comparator to support the claims in the labeling at altitudes up to 10745 feet have no significant effect on blood glucose measurements.

3. Sample volume study
   To assess the minimum sample volume of the Tyson Bio HT100 Blood Glucose Monitoring System, venous whole blood samples from volunteers were collected with K3-EDTA vacutainer tubes and were spiked with B-D- Glucose to four glucose concentrations (54.0, 117.0, 234.0 and 331.0 mg/dL). Blood samples were test with 10 measurements obtained from 10 meter with each level of blood sample using 3 different lots. Different testing volumes (0.5, 0.7, 1.0 ul) of each level were evaluated for accuracy.

The study results support the sponsor's claim that 0.7ul is the minimum sample volume required. The meter has an insufficient sample volume feature that was validated to demonstrate that the feature functions as intended.

4. Test System Operating Conditions:
   Operating conditions studies were performed using three test strip lots and ten meters, with venous blood altered to glucose concentrations of 41 mg/dL, 123 mg/dL and 345 mg/dL. Testing with the Tyson Bio HT100 Blood Glucose Monitoring System was performed at the combination of extremes of claimed temperature and humidity operating conditions and results compared to an established laboratory method (YSI). Results support the claims in the labeling that the test system can be used at temperatures from 50° to 104°F (10-40°C) and relative humidity of 10-90%.

5. Infection control studies:
   The device system is intended for single-patient use. Disinfection efficacy studies were performed on the external meter materials demonstrating removal of the HBsAg antigen with the chosen disinfectant, Clorox Bleach Germicidal Wipes (EPA Registration #67619-12). Robustness studies were performed by the sponsor demonstrating that there was no change in performance or external materials of the meters after 550 cleaning and disinfection cycles comprised of 1100 wipes. The robustness studies support 3 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6. EMC Testing:
   The sponsor provided appropriate documentation certifying that electromagnetic (EMC) testing was performed and the Tyson Bio HT100 Blood Glucose Monitoring System and the Tyson Bio HT100-B Blood Glucose Monitoring System were found to be compliant.

7. This device was cleared after the FDA issued final guidance documents for prescription use blood glucose monitoring systems (BGMS) and over-the-counter use blood glucose monitoring systems (SMBG). However, the recommendations in the guidance documents were not followed for this device since the studies were conducted prior to the finalization of the guidance documents.

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.