

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

A. 510(k) Number:

k072854

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative amperometric Assay.

E. Applicant:

Tyson Bioresearch Inc.

F. Proprietary and Established Names:

Diachex Basic Blood Glucose Monitoring System
Diachex Superb Blood Glucose Monitoring System
Diachex Vigor 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
CGA - Glucose Oxidase, Glucose

4. Panel:

75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

The DIACHEX BASIC / DIACHEX SUPERB / DIACHEX VIGOR Blood Glucose Monitoring System is intended for use in the quantitatively measurement of glucose (sugar) in fresh capillary whole blood from the fingertip and the alternative sites: the palm and the forearm. The DIACHEX BASIC / DIACHEX SUPERB / DIACHEX VIGOR Blood Glucose Test Strips are for testing outside the body (in vitro diagnostic use). The DIACHEX BASIC / DIACHEX SUPERB / DIACHEX VIGOR 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. It is not intended for the diagnosis of

or screening for diabetes mellitus. The alternative site testing in the systems can be used only during steady-state blood glucose conditions. It is not intended for neonatal testing.

3. Special conditions for use statement(s):

For Over-the-Counter use.

The alternative site testing in the DIACHEX BASIC / DIACHEX SUPERB / DIACHEX VIGOR Blood Glucose Monitoring Systems can be used only during steady-state blood glucose conditions.

Alternative site testing (AST) should ONLY be used in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since the last meal)
- Two hours or more after taking insulin
- Two hours or more after exercise

4. Special instrument requirements:

DIACHEX BASIC / DIACHEX SUPERB / DIACHEX VIGOR Blood Glucose Meters

I. Device Description:

The DIACHEX BASIC / DIACHEX SUPERB / DIACHEX VIGOR Blood Glucose Monitoring Systems each consist of five main components: the blood glucose meter, test strips, control solutions (3 levels of DIACHEX control solutions), Glucose Chip, and the lancing device with lancets. The sponsor recommends that only corresponding Diachex test strips and control solutions specified in the manual be used with the blood glucose meters. The performance of the test strips is verified by the control solutions.

J. Substantial Equivalence Information:

1. Predicate device name(s):

DIACHEX Blood Glucose Monitoring System

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

k062829

3. Comparison with predicate:

Similarities

The sponsor claims that there were no changes to the main electronic component, function of the meter, and detection algorithm. Additionally, blood glucose test strips are identical to the DIACHEX blood glucose test strips cleared with the predicate device. The differences between the new device and the predicate are based on the changes in the meter's software, LCD display, package labeling, and addition of alternate site testing use of the palm and the forearm.

Differences

Item	Proposed Device		Predicate DIACHEX (k062829)
	DIACHEX BASIC	DIACHEX SUPERB and DIACHEX VIGOR	
Blood Sample	Fingertip, Palm, and Forearm	Fingertip, Palm, and Forearm	Fingertip
Reminder alarm	Not present	4 user alarm settings	Not present
Hypoglycemic and hyperglycemic alarm	Not present	2 user alarm settings	Not present
PC download option	RS232	RS232	Not present
LCD Display	No difference to predicate	Alarm, strip, code, and control solution	-
Option of Average results	14 days	14 days	7, 14, and 30 days

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

L. Test Principle:

Glucose measurement is based on electrochemical biosensor technology using the enzyme glucose oxidase. The glucose in the sample is oxidized to produce gluconic acid. The electrical current resulting from this enzymatic reaction is measured and correlated to glucose concentration by the meter. The magnitude of the current is proportional to the concentration of glucose in the sample. The test strip is calibrated to display the equivalent of plasma glucose values to allow comparison of results with laboratory methods.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The sponsor evaluated within-day precision of the device using whole blood samples spiked with five different glucose concentrations (30-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, and 251-400 mg/dL) tested using one test strip lot and 10 glucose meters. All blood samples were maintained at hematocrit level of 42%. Each combination of multivariate factors was evaluated using 10 measurements. The sponsor did not conduct day-to-day precision studies.

Repeatability (within-day precision)

Sample level YSI (mg/dL)	Predicate Device (DIACHEX)			DIACHEX SUPERB			DIACHEX BASIC		
	Mean	SD	CV%	Mean	SD	CV%	Mean	SD	CV%
44.6	44.9	3.4	7.6	43.9	3.3	100	44.4	3.7	8.3
86.2	82.9	3.9	4.7	83.9	4.3	100	83.2	4.0	4.8
134	133	5.1	3.9	132	4.8	100	134	5.0	3.7
227	225	5.6	2.5	227	5.1	100	228	5.4	2.4
367	367	7.1	1.9	371	7.4	100	369	8.4	2.3

b. Linearity/assay reportable range:

The sponsor used whole blood samples from volunteers and spiked with B-D-Glucose to desired concentrations. The sponsor used 10 different levels (YSI values: 23.2 mg/dL, 46.2 mg/dL, 84.4 mg/dL, 132 mg/dL, 178 mg/dL, 226 mg/dL, 346 mg/dL, 452 mg/dL, 513 mg/dL, 581 mg/dL) covering the glucose range of 20 – 600 mg/dL. The samples were evaluated using 10 meters generating 10 values for each level. The values generated were compared with YSI generated values. The sponsor's criterion to be acceptable was the measurements determined by predicate and proposed devices are within 10% bias of the reference values by YSI 2300. The linear regression analysis of data generated is given in the table below.

Regression	Predicate (DIACHEX)	DIACHEX SUPERB	DIACHEX BASIC
Slope	1.00	0.99	0.98
Intercept	1.74	3.38	3.36
R2	0.9995	0.9996	0.9998
sy.x	6.6	5.9	5.6

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

The sponsor states that traceability and stability were previously cleared under k062829.

d. Detection limit:

The sponsor has not conducted studies to determine the limit of detection (LOD), however, as supported by linearity studies, the sponsor has established the measuring range of 20 - 600 mg/dL for DIACHEX BASIC / DIACHEX SUPERB / DIACHEX VIGOR Blood Glucose Monitoring Systems Blood Glucose Monitoring Systems.

e. Analytical specificity:

The sponsor stated that analytical specificity was previously cleared under k062829. The sponsor claims that Acetaminophen, Ascorbic acid, and Uric acid under normal blood or normal therapeutic levels do not significantly affect results, while abnormally high concentrations will cause inaccurate results. The sponsor also claims that cholesterol up to 500 mg/dL, or triglycerides up to 2000 mg/dL do not significantly affect results. As previously cleared in the predicate device (k062829), the sponsor

claimed that altitude test conducted for elevation up to 7545 feet showed bias level less than 15%. The sponsor also claims hematocrit levels between 35-55% do not affect the results.

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

2. Comparison studies:

a. *Method comparison with predicate device:*

The sponsor conducted accuracy studies to demonstrate that the DIACHEX BASIC / DIACHEX SUPERB / DIACHEX VIGOR Blood Glucose Monitoring Systems are equivalent to a standard reference method (YSI-2300). Samples from 102 volunteers with glucose concentrations distributed over the range of 44 – 434 mg/dL were evaluated. All participants claimed to be in glucose steady state. Percent distribution of the samples corresponding to the glucose concentration ranged as follows: <50 mg/dL – 3.9%; 50-80 mg/dL – 14.7%; 80-120 mg/dL – 18.6%; 120-200 mg/dL – 28.4%; 200- 300 mg/dL – 17.6%; 300-400 mg/dL – 14.7%; and >400 mg/dL – 2.0%. The values obtained were compared with the values generated using YSI. Based on data analysis, device met the minimum system accuracy requirement established according to the ISO 15197 guidelines, which is that 95% of samples will be within 15% of the reference for glucose concentrations < 75 mg/dL and within 20% of the reference for glucose concentrations ≥ 75 mg/dL. Linear regression analysis of the lay user and technician values compared with YSI values are summarized below.

DIACHEX Blood glucose meters vs. YSI-2300 reference method

Lay User Fingertip (N=102)	Predicate DIACHEX	DIACHEX SUPERB	DIACHEX BASIC
slope	1.01	0.99	0.98
y=intercept	0.22	0.99	0.13
R square	0.9795	0.9774	0.9813

DIACHEX Blood glucose meters vs. YSI-2300 reference method

Technician Fingertip (N=102)	Predicate DIACHEX	DIACHEX SUPERB	DIACHEX BASIC
slope	1.00	1.02	0.97
y=intercept	-0.33	-2.08	2.77
R square	0.9820	0.9814	0.9813

The sponsor's alternate site testing (AST) is limited to the palm and the forearm. Samples from 125 volunteers and 10 contrived samples were evaluated. The contrived samples, tested by the technicians only for fingertip testing, ranged from 29.7 to 43.2 mg/dL and from 490 to 579 mg/dL. All participants claimed to be in glucose steady state. Percent distribution of the 125 samples corresponding to the glucose concentration ranged as follows: <50 mg/dL – 1.6%; 50-80 mg/dL – 16%; 80-120 mg/dL – 22.4%; 120-200 mg/dL – 27.2%; 200- 300 mg/dL – 17.6%; 300-400

mg/dL – 11.2%; and >400 mg/dL – 2.4%. The glucose values based on YSI ranged from 47.3 to 471 mg/dL and hematocrit ranged from 33% to 55%. The volunteers were first requested to test themselves using the fingertip and alternate sites followed by a trained technician performing the test. The values obtained were compared with the values generated using YSI. The results met the AST acceptance criteria that was based on the acceptance criteria for accuracy according to the ISO 15197 guidelines, which is that 95% of samples will be within 15% of the reference for glucose concentrations < 75 mg/dL and within 20% of the reference for glucose concentrations ≥ 75 mg/dL. The linear regression analysis conducted is summarized in the following table for DIACHEX SUPERB.

Comparison (Lay User)	N	Slope and Y-intercept	R ²
Finger vs. YSI	125	y= 1.03x+0.66	0.9787
Palm vs. YSI	125	y=1.03x+2.61	0.9781
Palm vs. fingertip	125	y=0.99x+2.55	0.9861
Forearm vs YSI	123	y=1.01x+0.83	0.9767
Forearm vs. fingertip	123	y=0.98x+0.94	0.9835

The distribution of glucose differences between the AST and YSI for glucose concentration less than 75 mg/dL is given below.

Lay User	Difference within ± 5 mg/dL	Difference within ± 10 mg/dL	Difference within ± 15 mg/dL
Palm vs. YSI	12/18	15/18	18/18
Forearm vs YSI	11/18	15/18	18/18

The distribution of glucose differences between the AST and YSI for glucose concentration greater than or equal to 75 mg/dL is given below.

Lay User	Difference within $\pm 5\%$ mg	Difference within $\pm 10\%$	Difference within $\pm 15\%$	Difference within $\pm 20\%$
Palm vs. YSI	40/107	75/107	93/107	93/107
Forearm vs YSI	44/105	80/105	94/105	94/105

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):

4. Clinical cut-off:

Not Applicable.

5. Expected values/Reference range:

Based on the published literature, the sponsor included the following Expected Values for normal glucose levels in their strip labeling:

Status	Plasma glucose range for people without diabetes (mg/dL)
Before meals	70-110
2 hours after meals	<120

Source: American Diabetic Association Clinical Practice Recommendations 2003

N. Instrument Name:

DIACHEX BASIC / DIACHEX SUPERB / DIACHEX VIGOR Blood Glucose Monitoring Systems

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 reviewed applicant's Hazard Analysis and software development processes for this line of product types in k052818. Additionally, in this submission, the sponsor provided data to support the accuracy of PC downloaded feature that allows the user to download glucose meter readings to a personal computer. Only the memory information within BASIC/SUPERB/VIGOR glucose meters can be downloaded to PC through RS-232 port and can be cleared by software. The sponsor did not include the software for managing diabetes into this submission. The sponsor also provided all Over The Shelf Software (OTSS) components and related design validation verification and testing activities.

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, the palm, and the 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 strip is provided with each batch of test strips to calibrate the meter for that batch. No further calibrations are required of the user.

6. Quality Control:

Glucose control solutions at three different concentrations to be run with this device are available for use but not supplied with the device. An acceptable range for each control level is printed on the test strip vial label. The user is referred to the troubleshooting section of the owner's manual if control results fall outside these ranges. There are three previously cleared DIACHEX Control Solutions (Low, Normal, and High) for each of the three meters that are available for the user to choose from. The sponsor recommends the use of at least two controls solutions, normal with the user's choice of either high or low control solution to check the accuracy of the system.

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

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.