

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

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

k072274

**B. Purpose for Submission:**

New device

**C. Measurand:**

Whole blood glucose

**D. Type of Test:**

Quantitative (glucose oxidase)

**E. Applicant:**

Bestgen Biotech Corporation

**F. Proprietary and Established Names:**

Major III Blood Glucose Monitoring System

**G. Regulatory Information:**

1. Regulation section:

21 CFR 862.1345 Glucose Test System

2. Classification:

Class II (assay)

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 Major III Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary blood from the fingertip. Testing is done outside the body (in vitro diagnostic use). It is indicated for use at home (over the counter [OTC] ) by persons with diabetes, or in clinical setting by health care professionals, as an aid to monitor the effectiveness of diabetes control.

3. Special conditions for use statement(s):

Not intended for the diagnosis of or screening for diabetes and not intended for use on neonates. The device should not be used for patients who are dehydrated, in shock, critically ill or in a hyperosmolar state.

4. Special instrument requirements:

Major III Blood Glucose Meter

**I. Device Description:**

The Major III Blood Glucose Monitoring System is comprised of the Major III Blood Glucose Meter, Major III Blood Glucose Test Strips, Major Control Solutions, lancing device, and code card.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Diacare Easy Check Blood Glucose Monitoring System

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

k062538

3. Comparison with predicate:

<b>Similarities</b>		
Item	Device	Predicate
Detection method	amperometry	Same
Enzyme	Glucose oxidase	Same
Mediator	K hexacyanoferrate	Same
Sample type	Whole blood	Same
Test range	30-600 mg/dL	Same
Temperature range	2 -30 °C	Same
Humidity range	20-80%	Same
<b>Differences</b>		
Item	Device	Predicate
Sample volume	0.8 uL	1.5 uL
Test time	8 seconds	9 seconds
Hct range	30-55%	30-50%
Test sample	Fingertip	Fingertip and forearm
Memory	960	180

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

- ISO 15197: 2003, In Vitro Diagnostic Test Systems – Requirements for Blood Glucose Test Systems for Self Managing Diabetes Mellitus
- ISO 13485: 2003, Design, Manufacture and Distribution of Medical Devices for the Measurement of Blood Glucose
- IEC 61010-2-101, Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use
- CLSI EP6-A, Evaluation of the Linearity of Quantitative Analytical Methods
- CLSI EP5-A, Evaluation of Precision Performance of Clinical Chemistry Devices
- CLSI EP7-P, Interference Testing in Clinical Chemistry; Proposed Guideline
- Guidance for Industry and FDA Staff Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

**L. Test Principle:**

The Major III Blood Glucose Monitoring System employs amperometric technology, using glucose oxidase. When blood is applied to the test strip, electrons are formed by the reaction between glucose oxidase and blood glucose. The resulting electric current is measured by the meter and correlates with the concentration of glucose in the blood sample.

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

### 1. Analytical performance:

#### a. *Precision/Reproducibility:*

The sponsor evaluated within-day and between day precision of the device using whole blood samples spiked with 5 different glucose concentrations, two test strip lots, and 10 meters. Ten replicate measurements were tested for each concentration each day, for a total of 20 days. Results for each test strip lot are summarized in the tables below:

Lot 1

mean mg/dL	Within-run SD	Between run SD	CV%
49	2.8	1.4	6.8
71	2.8	2.0	5.3
113	2.7	2.6	4.4
216	5.6	1.9	3.8
335	7.1	4.2	3.7

Lot 2

mean mg/dL	Within-run SD	Between run SD	CV%
50	2.9	1.3	6.8
75	2.7	1.4	4.4
111	3.2	1.4	3.9
211	4.7	2.1	3.4
332	9.6	4.9	3.6

In addition, the sponsor evaluated five replicates of two levels of control material with two test strip lots and 20 meters. Results are summarized in the following table:

Lot 1

	Mean mg/dL	SD	CV%
Level 1	100	4.5	4.6
Level 2	238.3	7.8	3.3

Lot 2

	Mean mg/dL	SD	CV%
Level 1	97.9	4.7	4.8
Level 2	234.7	11.4	4.9

*b. Linearity/assay reportable range:*

The measuring range of the device is 30-600 mg/dL. Testing was performed using oxygenated venous blood samples at 10 different blood glucose levels, ranging from 30-687 mg/dL, tested on 2 lots of test strips. The YSI was used as the reference method. The linear regression for lot 1 was  $y = 1.033x - 7.5088$ ,  $r^2 = 0.9991$ , and the linear regression of lot 2 was  $y = 1.0366x - 10.141$ ,  $r^2 = 0.9994$ .

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

The control solutions are manufactured by Diacare Corporation and previously cleared under k062538. Bestgen recommends the use of these control solutions with their test system.

*d. Detection limit:*

The detection limit is 30 mg/dL. See linearity/assay reportable range above.

*e. Analytical specificity:*

Three endogenous and seven exogenous substances were tested for interference on this assay at a low and high glucose concentration. Two test strip lots and ten meters were used in this study. Of those substances tested, ascorbic acid greater than 1.2 mg/dL, dopamine greater than 30 mg/dL, L-Dopa greater than 10 mg/dL, and uric acid greater than 7 mg/dL showed interference

The effect of hematocrit was evaluated in a study using samples with 5 glucose concentrations (30, 70, 150, 260, and 600 mg/dL) and varying hematocrit levels between 30-70%. Each glucose level/hematocrit combination was tested on 10 meters, by comparing the results of samples at each of the varying hematocrit levels to the sample of the same glucose concentration at a normal (40%) hematocrit level. The results for hematocrit levels are presented below. The sponsor chose an acceptable hematocrit range of 30-55%:

Hct(%)		20	25	30	40	50	55	60	65	70
Difference (mg/dL)	30	6.1	5.7	4.2		-2.2	-2.7	-4.1	-5.6	-8.3
	70	16.0	14.9	8.0		-6.1	-8.3	-11.3	-14.5	-20.6
Bias (%)	150	26.4	20.5	17.3		-14.2	-17.4	-29.0	-34.3	-38.6
	260	25.9	19.6	16.1		-11.3	-18.0	-29.4	-34.7	-43.2
	600	31.1	24.4	17.0		-13.0	-17.9	-34.0	-40.8	-45.3

Temperature and humidity studies were performed and showed that the meter can be used at temperatures from 10-40°C and at relative humidity ranging from 20-80%.

Altitude studies were conducted with whole blood samples at 5 concentrations (56, 75, 123, 238 and 478 mg/dL) and with 2 levels of controls (normal and high). Study results demonstrated no interference at elevations up to 6266 feet above sea level.

*f. Assay cut-off:*

Not applicable

## 2. Comparison studies:

*a. Method comparison with predicate device:*

A method comparison study was performed with two hundred forty fingerstick patient samples. The study participants obtained and tested their own samples using only the directions in the labeling, followed by a trained technician performing testing on the same individuals. The technicians also obtained venous samples from which plasma aliquots were assayed on the YSI instrument. These samples ranged in concentration from 50-505 mg/dL. To obtain samples with values < 50 mg/dL, the sponsor followed the procedure in section 7.3.1.2 in the ISO 15197 standard, using samples from 10 of the study participants. These 10 samples are included in the regression analysis of samples tested by the technicians, accounting for a total of 240 samples. The total number of samples tested by the patients was 230. The linear regressions were as follows:

Patient vs YSI  $y = 0.919x + 11.73, r^2 = 0.9731$

Healthcare professional vs YSI  $y = 0.982x + 0.45, r^2 = 0.978$

Patient vs healthcare professional  $y = 0.964x + 4.44, r^2 = 0.990$

For samples < 75 mg/dL

<b>Sample</b>	<b>Within <math>\pm</math> 5 mg/dL</b>	<b>Within <math>\pm</math> 10 mg/dL</b>	<b>Within <math>\pm</math> 15 mg/dL</b>
<b>Patient</b>	19/23 (83%)	23/33 (100%)	23/23 (100%)
<b>Technician</b>	29/33 (87%)	33/33 (100%)	33/33 (100%)

For samples  $\geq$  75 mg/dL

<b>Sample</b>	<b>Within <math>\pm</math> 5 mg/dL</b>	<b>Within <math>\pm</math> 10 mg/dL</b>	<b>Within <math>\pm</math> 15 mg/dL</b>	<b>Within <math>\pm</math> 20 mg/dL</b>
<b>Patient</b>	90/207 (43%)	154/207 (74%)	181/207 (87%)	200/207 (97%)
<b>Technician</b>	66/207 (32%)	138/207 (67%)	177/207 (94%)	204/207 (97%)

*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):*

See section 2a above

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Expected blood glucose levels for people without diabetes (referenced from Joslin Diabetes Manual):

Before breakfast - 70-105 mg/dL

Before lunch or dinner - 70-110 mg/dL

One hour after meals - less than 160mg/dL

Two hours after meals - less than 120 mg/dL

Between 2 and 4 a.m. - greater than 70 mg/dL

**N. Instrument Name:**

Major III Blood Glucose Meter

**O. System Descriptions:**

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for each additional reading.

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 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 card is provided with each batch of test strips to calibrate the meter for that batch.

6. Quality Control:

Glucose control solutions at two concentrations should be run with this device. An acceptable range for each control is printed on the test strip vial. The user is instructed to contact the Customer Help line if control results fall outside these ranges.

**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.