510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number: k032029

B. Analyte: whole blood glucose

C. Type of Test: Quantitative, utilizing Glucose Oxidase technology.

D. Applicant: BT Medical

E. Proprietary and Established Names: BTg Smartest Glucose Test System

F. Regulatory Information:
  1. Regulation section:

  21 CFR 862.1345 Glucose Test System
  21 CFR 862.1660 Quality Control Material

  2. Classification:

  Class II

  3. Product Code:

  NBW, System, Test, Blood Glucose, Over The Counter
  CGA, Glucose Oxidase, Glucose
  JJX, Single (Specified) Analyte Controls

  4. Panel:

  Chemistry (75)

G. Intended Use:

  1. Indication(s) for use:

  The BTg Smartest Glucose test system is intended for use in the quantitative measurement of glucose in whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

2. Special condition for use statement(s):
Provides plasma equivalent results.
Do Not Use for neonatal specimens.
3. Special instrument Requirements:
N/A

H. Device Description:

The BT Medical BTg Smartest Blood Glucose Monitoring System consists of the Glucose Meter, Lancing Device, 10 Lancets, User Manual, Carrying Case, Glucose Strips, 1 vial of Normal Control, and 1 vial of High Control.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Bayer Elite with the Ascensia Elite test strips.

2. Predicate K number(s):
K991242

3. Comparison with predicate:

Similarities		
Item	**Predicate Device**	**Proposed Device**
	Bayer ELITE (K991241)	**BTG (K032029)**
Similarities	1. Monitors glucose using whole blood. 2. Directly displays results without requiring calculation. 3. Test Principle includes measuring a current produced by a chemical reaction. 4. Test Principle: Uses glucose oxidase reaction. 5. Measuring Range: 20 to 600 mg/dL.	1. Monitors glucose using whole blood. 2. Directly displays results without requiring calculation. 3. Test Principle includes measuring a current produced by a chemical reaction. 4. Test Principle: Uses glucose oxidase reaction. 5. Measuring Range: 20 to 600 mg/dL.
	ELITE	**BTG**
Differences	1. Size: Meter is 97.8 x 56 x 14.5 mm. 2. Measuring time: 30 seconds.	1. Size: Meter is 115 x 44 x 21, which is longer and slimmer, but thicker than the ELITE. 2. Measuring time: 15 seconds.

J. Standard/Guidance Document Referenced (if applicable):
NCCLS Standards, EN 1441(1997) Medical Devices – Risk Analysis, FDA guidance document; Guidance for the content of Premarket Submissions for Software contained in Medical Devices, Clarke Error Grid Analysis, EN60601-1-2(2002) Medical Electrical Equipment

K. Test Principle:
Electrochemical biosensor technology using glucose oxidase is used. The strip uses the enzyme glucose oxidase to produce a current that will stimulate a chemical reaction. This reaction is measured by the Meter and displayed as your blood glucose result.

L. Performance Characteristics (if/when applicable):
    1. <u>Analytical performance:</u>
         a. *Precision/Reproducibility:*

Precision describes the variation between readings. A test system that gives equivalent values every time is said to be precise.

A laboratory study was conducted using venous heparinized blood samples. These were adjusted to a broad range of glucose values by adding glucose to the blood. The results from a single precision run are shown in the table below.

Number of tests	*20*	*20*	*20*	*20*	*20*
Glucose value in mg/dL	*47.7*	*91.3*	*165.8*	*199.4*	*412.7*
SD	*3.69*	*7.19*	*9.40*	*11.02*	*25.03*
% CV	*7.74*	*7.87*	*5.67*	*5.53*	*6.06*

This means that repeated results should vary by less than 8%

         b. *Linearity/assay reportable range:*
Linearity testing was performed to confirm that the device is capable of accurately reporting results in the claimed dynamic measuring range. 60 samples were prepared by allowing a sample to glycolyze to 17 mg/dL then spiking an aliquot to a concentration of 612 mg/dL and making 11 dilutions of the high and low samples. The samples were analyzed 5 times for glucose on both the predicate device Bayer ELITE and on the BT Medical BTg Smartest. The regression results are in the table below.

	BTg Glucose vs. Bayer ELITE Glucose
Range of Samples	*17 to 612 mg/dL*
n	*60*
Slope	*1.0241*
y-intercept (mg/dL)	*-4.8*
Correlation Coefficient (r)	*0.9992*

This system can measure glucose results from 20-600 mg/dL

    c. *Traceability (controls, calibrators, or method):*
     None stated

    d. *Detection limit:*
     N/A

    e. *Analytical specificity:*

Interference testing was conducted to determine the effect of select endogenous and exogenous substances. A series of test samples, systematically varying in the concentration of the interferents, was prepared by making quantitative, volumetric mixtures. The substances and concentrations of the interferents are recommended at NCCLS EP7-P.

Conclusions:

The BTG Smartest Glucose Test Strip showed no significant interference due to the substances tested, with the exception of ascorbic acid (Vitamin C), and dopamine.

- Vitamin C of greater than 0.75 mg/dL in blood decreased the glucose result.
- Dopamine greater than 3.25 mg/dL in blood increased the glucose result.

    f. *Assay cut-of:*
     N/A
  2. Comparison studies:
    a. *Method comparison with predicate device:*

One hundred fifty-four (154) subjects at three sites, including three point-of-care (POC) sites (physician offices) tested their own glucose and were tested by a professional using the BTg Smartest Glucose Test System and the Bayer ELITE (predicate). Fingerstick capillary blood was the sample. The BTg Smartest was calibrated using 10 levels of whole blood glucose and fitted to a straight line. The correlation data is listed in the table that follows:

Accuracy Statistics Summary

	BTG Professional vs. Bayer Elite	BTG Consumer vs. Bayer Elite
Number of Patients (n)	154	154
Number of sites	3	3
Slope	0.9565	0.9601
Upper 95% Cl for slope	1.000	1.0048
Lower 95% Cl for slope	0.9123	0.9154
Intercept	7.375	5.882
Upper 95% Cl for intercept	0.960	-0.710
Lower 95% Cl for intercept	13.79	12.474
Standard Error of the Estimate (mg/dL)	17.900	18.395

Correlation Coefficient (r)	0.9620	0.9603
Range of Glucose Values (mg/dL)	58 – 447	43 – 462
Mean of Elite method (mg/dL)	132	132
Mean of BTG method (mg/dL)	134	133
Bias (measurement error) at 126 mg/dL	1.89	0.85
Average bias (mg/dL)	1.63	0.61

    b. *Matrix comparison:*
      N/A

   3. Clinical studies:
     a. *Clinical sensitivity:*
       N/A

     b. *Clinical specificity:*
       N/A

     c. *Other clinical supportive data (when a and b are not applicable):*

   4. Clinical cut-off:
     N/A

   5. Expected values/Reference range:

     70-110 mg/dL- adult fasting glucose reference range according to Norbert Tietz's Fundamentals of Clinical Chemistry

     126 mg/dL – the fasting glucose level that is diagnostic for Diabetes according to the clinical practice guidelines of the American Diabetes Association

M. Conclusion:
  Based upon the information provided in this submission, this device is Substantially Equivalent to 21 CFR 862.1345, 75 NBW, System, Test, Blood Glucose, Over the Counter and 75 CGA Glucose Oxidase, Glucose.