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

A. 510(k) Number:
k041478

B. Purpose for Submission:
The purpose of this premarket notification is to modify the intended use/indications for use to include off-finger testing (alternative anatomical testing) for the BD Logic and BD Paradigm Link Blood Glucose Monitors

C. Measurand:
Glucose

D. Type of Test:
Quantitative, electrochemical biosensor

E. Applicant:
BD Medical – Diabetes Care

F. Proprietary and Established Names:
BD Logic and BD Paradigm Link Blood Glucose Monitoring Systems

G. Regulatory Information:

1. Regulation section:
   21CFR §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:
   Chemistry 75

H. Intended Use:

1. Intended use(s):
   The BD Logic and BD Paradigm Link Blood Glucose Monitoring Systems are intended to be used for the quantitative measurement of glucose in capillary whole blood.

2. Indication(s) for use:
   The BD Logic and BD Paradigm Link Blood Glucose Monitoring Systems are

intended to be used for the quantitative measurement of glucose in capillary whole blood. The monitors are intended for use by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. The BD Logic and the BD Paradigm Link are not intended for use in the diagnosis of or screening for diabetes mellitus and are not intended for use on neonates.

The BD Logic and the BD Paradigm Link are specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip, palm and forearm.

3. Special conditions for use statement(s):
   Provides plasma equivalent results.
   Forearm testing should only be done during times of steady state. Finger and palm (thenar and hypothenar) can be used during times when glucose is changing rapidly (dynamic states).

4. Special instrument requirements:
   Not Applicable

I. Device Description:

The BD Logic and BD Paradigm Link Blood Glucose Monitoring Systems consist of a blood glucose monitor, test strips, control solution, lancing device with adjustable depth setting and lancets. The Off-Finger Test Kit for alternative site testing is provided separately and consists of the Off-Finger Lancet Cap with a non-adjustable lancing depth and an Instruction Sheet.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   BD Logic Blood Glucose Monitoring System
   BD Paradigm Link Blood Glucose Monitoring System
   Therasense Freestyle Blood Glucose Monitoring System
   Bayer Glucometer Dex Diabetes Care System

2. Predicate 510(k) number(s):
   BD Logic - k022581
   BD Paradigm Link - k030531, k040603
   Therasense - k992684, k000582, k031260
   Bayer - k963500, k012205, k020210

3. Comparison with predicate:

	Principal Device ***BD Blood Glucose Monitors***	***Predicate Devices*** ***BD Blood Glucose Monitors*** **k022581, k030531, k040603**
Indications for Use	BD Logic and Paradigm Link Blood Glucose Monitoring Systems are intended to be used for the quantitative measurement of glucose in whole blood. The monitors are intended for use by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. BD Monitors are not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. The BD Logic and Paradigm Link are specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip, palm, and forearm.	BD Logic and Paradigm Link Blood Glucose Monitoring Systems are intended to be used for the quantitative measurement of glucose in whole blood. It is intended for use by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. The BD Logic and Paradigm Link are specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip.
System components	• Meter • Test Strips • Lancing device and lancets • Off-Finger Lancet Cap and Fingertip Lancet Cap	• Meter • Test Strips • Lancing Device and lancets • Fingertip Lancet Cap only
Test Method	Glucose oxidase/Amperometric detection	Glucose oxidase/Amperometric detection
Sample	Capillary Whole Blood	Capillary Whole Blood
Test Strip Volume	0.3 μL	0.3 μL
Sample application	End of strip capillary draw	End of strip capillary draw
Test range	20 - 600 mg/dL	20 - 600 mg/dL
Hematocrit range	25 - 60%	25 - 60%
Test Site(s)	▪ Fingertip ▪ Palm Heel ▪ Palm Side ▪ Forearm	Fingertip
Lancet	BD 33G Lancet	BD 33G Lancet

	Principal Device ***BD Logic and Paradigm Links*** **k022581, k030531, k040603**	**Predicate Device** **TheraSense FreeStyle** **k992684, k000582, k031260**	**Predicate Device** **Bayer Glucometer Dex** **k963500, k012205, k020210**
Indications for Use	BD Blood Glucose Monitors are intended to be used for the quantitative measurement of glucose in whole blood. The monitors are intended for use by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. BD monitors are not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. The BD Blood Glucose Monitors are specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip, palm, and forearm.	The FreeStyle Blood Glucose monitoring 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 at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and it is not intended for use on neonates.	The Glucometer Dex Blood Glucose Test System is for the self-monitoring of blood glucose as an adjunct to the care of persons with diabetes.
Off-Finger test components	• Meter • Test Strips • Off-Finger Lancing Device	• Meter • Test Strips • Off-Finger Lancing Device	• Meter • Test Strips • Off-Finger Lancing Device
Off-Finger Sites	▪ Palm Heel ▪ Palm Side ▪ Forearm	▪ Palm ▪ Forearm ▪ Abdomen ▪ Thigh	▪ Palm ▪ Forearm ▪ Abdomen ▪ Thigh
Alternate Anatomical Site/Fingertip equivalence	Yes - Palm	Yes - Palm	No
Enzyme	Glucose oxidase	Glucose Dehydrogenase	Glucose oxidase
Detection Methodology	Electrochemical	Electrochemical	Electrochemical
Sample	Capillary Whole Blood	Capillary Whole Blood	Capillary Whole Blood
Sample application	End of strip capillary draw	End of strip capillary draw	End of strip capillary draw
Test range	20 - 600 mg/dL	20 – 500 mg/dL	10 – 600 mg/dL
Test time	5 seconds	15 seconds	30 seconds
Hematocrit range	25 - 60%	30-60 %	20 - 55%

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

Review Criteria Assessment of Portable Blood Glucose Monitoring In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase or Hexokinase Methodology – FDA Guidance Document

AdvaMed Points to Consider for Glucose Monitoring Devices Intended for Alternative Site Testing

L. Test Principle:

The user obtains a blood sample using a conventional lancing technique. The user inserts a test strip into the meter, which turns the meter on. When the strip is touched to the blood drop, the test strip is filled by capillary action. The blood sample volume required is approximately 0.3 microliters, which can be obtained from the finger or other areas of the body such as the palm or forearm. Test results are displayed in about 5 seconds.
The test systems use electrochemical biosensor technology. When blood is applied to the test strip, reagents on the strip react with the blood and a current is generated. The monitors employ amperometric technology to measure the glucose concentrations in the blood sample by measuring the amount of current that is generated when glucose reacts with the glucose oxidase on the test strip. The result is the generation of current across the electrodes, which is proportional to the concentration of glucose present in the whole blood sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:
   The precision/reproducibility was cleared with the original 510(k) for the BD Logic (k022581).

   b. Linearity/assay reportable range:
   The linear range was cleared with the original 510(k) for the BD Logic (k022581).

   c. Traceability, Stability, Expected values (controls, calibrators, or methods):
   Not Applicable

   d. Detection limit:
   Detection limits of both systems is 20 – 600 mg/dl (1.1 – 33.3 mmol/L).
   The detection limit was cleared with the original 510(k) for the BD Logic (k022581)
   .
   e. Analytical specificity:
   The analytical specificity was cleared with the original 510(k) for the BD Logic (K022581).

   f. Assay cut-off:
   Not Applicable

2. Comparison studies:
   a. Method comparison with predicate device:

Clinical accuracy as compared to the predicate devices was demonstrated in the original 510(k) for the BD Logic (k022581).

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*):
The performance of the BD Logic and BD Paradigm Link Blood Glucose Monitoring Systems for alternative site testing was evaluated under fasting (steady state) and dynamic glycemic conditions. The results from each study were evaluated separately for usability, and correlation of off-finger and fingertip monitoring by users.

Fifty eight study subjects were enrolled in the steady-state evaluation. The resulting linear regressions from this study comparing lay user to healthcare professional (hcp) were as follows:

Palm (thenar) vs fingerstick
Lay user $y = 0.955x + 0.54$,
Hcp $y = 1.030x – 2.36$
Palm (hypothenar) vs fingerstick
Lay user $y = 0.99x – 1.06$
Hcp $y = 0.995x + 2.28$
Forearm
Lay user $y = 0.959 + 0.71$
Hcp $y = 1.0589 + 0.71$

Fifty six study subjects were enrolled in the dynamic change study. The subjects were fed and treated with insulin, and their blood glucose was analyzed every twenty minutes with duplicate YSI values. The peak rate of glucose change was achieved for all subjects with maximal rates either falling at more than –1mg/dL per minute or rising at more than 1 mg/dL per minute, and fifty-four subjects maintained a rate of change of greater than or equal to 1mg/dL per minute (positive or negative) for over a forty (40) minute period.
The resulting linear regressions from this study, comparing alternative site to fingerstick were as follows:

Palm (thenar) $y = 1.059x -2.73$
Palm (hypothenar) $y = 1.057x + 1.06$
Forearm (rubbed) $y = 0.990x + 12.01$
Forearm (not rubbed) $y = 0.986x + 15.12$

The mean percent error (MPE) compared to YSI by site was determined to be as follows:

Finger 9.14%
Palm (thenar) 8.71%
Palm (hypothenar) 9.80%
Forearm (rubbed) 11.50%
Forearm (not rubbed) 13.40%

The results of the clinical evaluations demonstrated that off-finger testing on the palm was equivalent to fingerstick testing and that forearm may differ from fingerstick because of physiological differences. Optimal lag time analysis demonstrated that forearm blood glucose testing lags fingerstick. The results of equivalence testing at a 10% significance level for MPE within ±10% demonstrated equivalent results for Palm- thenar and Palm - hypothenar.

During clinical evaluation of off-finger testing, it was observed that a small percentage (<3%) of samples appeared pink or clear after being applied to the test strip, indicating that the composition of the sample was mostly (or wholly) interstitial fluid. Although the results from these samples demonstrated the same accuracy as samples known to be blood, a warning was included in the Off-Finger Instructions for Use instructing the user not to use any sample that appeared pink or clear in color. A usability study was conducted to evaluate the ability of the users to comprehend this warning and to distinguish between acceptable samples (red, indicating blood), and unacceptable samples (pink or clear, indicating interstitial fluid samples). Forty two subjects each evaluated nine test strip samples composed of red, pink and clear samples in a randomized order. All subjects correctly indicated that 100% of pink and clear samples were unacceptable.

4. Clinical cut-off**:**
   Not Applicable

5. Expected values/Reference range:
   Not Applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.