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

A. 510(k) Number:

k080960

B. Purpose for Submission:

New device

C. Measurand:

Whole blood glucose and whole blood B-ketone

D. Type of Test:

Quantitative amperometric glucose oxidase and quantitative amperometric B-ketone

E. Applicant:

Abbott Diabetes Care, Inc.

F. Proprietary and Established Names:

Precision Xceed Pro Blood Glucose and B-Ketone Monitoring System

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345 Glucose Test System
   21 CFR 862.1435 Ketones (nonquantitative) test system

2. Classification:

   Class II (glucose)
   Class I (B-ketone), meets limitation to exemption, as per 21 CFR 862.9 (c)(5)

3. Product code:

   NBW – System, Test, Blood Glucose, Over the Counter

LFR - Glucose Dehydrogenase, Glucose
JIN - nitroprusside, ketones (urinary, non-quant.)

4. Panel:

   75, Clinical Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The Precision Xceed Pro Blood Glucose and B-Ketone Monitoring System is intended for in vitro (outside the body) diagnostic use for the quantitative measurement of glucose (D-glucose) in fresh capillary whole blood (fingertip), and of B-Ketone (beta-hydroxybutyrate) in fresh capillary whole blood samples. The Precision Xceed Pro System is for home (lay user) or professional use. The system is not for use in diagnosing diabetes mellitus, but is to be used as an aid in monitoring the effectiveness of diabetes control programs.

   Healthcare professionals may also use the product for the quantitative measurement of glucose in venous, arterial, or neonatal whole blood and ketone in venous blood, provided the sample is used within 30 minutes after collection.

3. Special conditions for use statement(s):
   • Not for screening or diagnosis of diabetes mellitus
   • Not for patients who are dehydrated, in shock, critically ill, or in a hyperosmolar state

4. Special instrument requirements:

   Precision Xceed Pro Monitor

I. Device Description:

The Precision Xceed Pro Blood Glucose and B-Ketone Monitoring System is comprised of the Precision Xceed Pro Monitor (same as meter cleared under k021960, with addition of ketone testing capability), Precision Xceed Pro Glucose Test Strips (cleared under k021960), Precision Xceed Pro B-Ketone Test Strips (same as strips cleared under k040814), and Precision/MediSense/Optium Control Solutions (controls previously cleared in k021960).

J. Substantial Equivalence Information:

1. Predicate device name(s):

Precision Xceed Pro Blood Glucose Monitoring System (for glucose)
Precision Xtra Advanced Diabetes Monitoring System (for B-ketone)

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

   k021960
   k040814

3. Comparison with predicate:

Specification	**Precision Xtra BGMS (K040814)**	**Precision Xceed Pro BGMS (Modified Device)**
SYSTEM SPECIFICATIONS		
Brand Name	Precision Xtra Diabetes Monitoring System	Precision Xceed Pro Blood Glucose and B-Ketone Monitoring System
Intended Use	Over the Counter and Professional Use	Over the Counter and Professional Use
Assay Time	20 seconds- glucose 10 seconds-ketone	Same
Calibration Method	ROM calibrator	Bar code scanner
Control Solution	Precision/Optium/MediSense Control Solutions	Same
MONITOR SPECIFICATIONS		
Measurement Type	Analog to Digital Converter	Same
Measurement Electronics	ASIC	ASIC
Communications Connector	Data Cable	Same
User Interface	Icon driven	Menu driven
Test Strip Interface Port	Part 120-002	Same
Power Source	1 – Lithium battery	2 – AA batteries

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

CLSI EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition.

IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety

IEC 60601-1-1 Medical Electrical Equipment - Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems, 1992-06 Amendment 1, 1995-11

IEC 60601-1-2 (First Edition, 1993-04), Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility - Requirements and Tests

L. Test Principle:

The Precision Xceed Pro Blood Glucose and B-Ketone Monitoring System measures glucose electrochemically. The glucose biosensor is capable of determining glucose oxidized by the enzyme (Glucose Dehydrogenase, GDH-NAD) catalyzed reaction with Nicotinamide Adenine Dinucleotide (NAD+) cofactor. The reduced form of NAD + (NADH) is re-oxidized by reaction with the electrochemical mediator, 1,10-phenanthroline quinone (1,10-PQ). The reduced mediator is re-oxidized via electron transfer at the electrode surface. This current is translated into a number by the monitor, after applying lot specific calibration information and after a 20 second countdown, a concentration value is presented to the user. In this same manner, the biosensor electrode utilizes the enzyme hydroxybutyrate Dehydrogenase (HBDH), which reacts with the beta-hydroxybutyrate (beta-ketone) concentration in the sample. This reaction is transferred to the monitor through an electrical current generated proportional to the level of beta-ketone in the sample. This current is translated into a number by the monitor, after applying lot specific calibration information and after a 10 second countdown, a concentration value is presented to the user.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. Precision/Reproducibility:

   Glucose precision was established in k021960.

   <u>B-ketone within-run precision</u> - Testing with blood was conducted using four Xceed meters for each of three lots of blood ketone test strips with three venous whole blood samples. Each blood was spiked to five 3-OHB (ketone) levels (0-0.75, 0.75-1.5, 1.5-3, 3-4.5 and 4.5-8.0 mmol/L). For each lot of test strips, twenty replicate measurements were performed for each blood and ketone level. Testing with control solution was conducted over two runs using four Xceed meters for each of three lots of blood ketone test strips with low, mid and high ketone control solution. For each run and lot of test strips forty replicate measurements were performed for each control solution level.

Results from testing with blood; the mean response, standard deviation (SD) and coefficient of variation (% CV) were calculated for each lot of test strips, blood, meter and ketone level. Mean results were then calculated for each ketone level by lot and over the three lots of test strips. Mean values for SD and % CV were calculated using root mean square (RMS). Results from testing with control solution; the mean response, SD and % CV were calculated for each lot of test strips, run, meter and control solution level. Mean results were then calculated for each control solution level by lot and over the three lots of test strips. Mean values for SD and % CV were calculated using root mean square.

Summary of results:

Range of within-run SD and % CV over 3 lots of test strips

Whole blood ketone level (mmol/L)				
0.51	0.95	1.90	4.12	6.37
SD (mmol/L)	SD (mmol/L)	% CV	% CV	% CV
0.02-0.04	0.02-0.05	3.7-4.0	3.2-3.6	3.0-3.2

Control solution ketone level (mmol/L)		
Low (0.78)	Mid (2.35)	High (4.19)
SD (mmol/L)	% CV	% CV
0.03-0.05	2.4-2.8	2.3-2.5

B-ketone between-run precision - Testing was conducted over twenty days using ten Xceed meters and three lots of blood ketone test strips with low, mid and high ketone control solution. For each meter, two replicates were performed on each day, lot of test strips and control solution level.

The mean response, standard deviation (SD) and coefficients of variation (% CV) were calculated for each lot of test strips and control solution level. Mean results were then calculated over the three lots of test strips. Mean values for SD and % CV were calculated using root mean square.

Summary of results:

Range of day to day (between-run) SD and % CV over 3 lots of test strips

Control solution ketone level (mmol/L)		
Low (0.81)	Mid (2.34)	High (4.15)
SD (mmol/L)	% CV	% CV
0.012-0.013	0.9-1.3	1.5-2.1

b. Linearity/assay reportable range:

Glucose linearity was established in k021960.

B-ketone linearity – The study was conducted over 2 days. On each day, capillary whole blood samples were collected from 20 donors. The capillary samples were spiked to varying ketone concentrations and distributed throughout the measuring range, from 0.01-8.0mmol/L. Three lots of test strips were tested. Duplicate measurements were performed for each lot of test strips, day and blood sample.

The sponsor's acceptance criteria of +/- 0.3mmol/L for ketone levels below 1.5mmol/L and +/- 10 % for ketone levels at or above 1.5mmol/L were met. The linear regressions for lot 1 was $y = 0.96x - 0.01$, $r^2 = 0.99$, for lot 2 was $y = 0.99x - 0.03$, $r^2 = 0.99$, and for lot 3 was $y = 0.95x + 0.01$, $r^2 = 1.00$. This testing also demonstrated that readings of "Hi" were consistently obtained for ketone levels > 8.0mmol/L.

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

Glucose controls traceability and stability was established in k021960.
Ketone controls traceability and stability was established in k040814.

d. Detection limit:

Glucose detection limit was established in k021960.

B-ketone limit of detection is 0.01mmol/L.

e. Analytical specificity:

Glucose analytical specificity was established in k021960.

Since the B-ketone test strips have not been modified since clearance in k040814, the B-ketone specificity established in k040814 is applicable.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Glucose accuracy was established in k021960.

B-ketone accuracy - A total of 96 samples with ketone values ranging from 0.03 to 5.8 mmol/L were evaluated on each of 3 strip lots run with the Precision Xceed Pro System and with the Randox Daytona 3-OHB method. The regression statistics were as follows:

	Slope (95% CI)	Intercept (mmol/L) (95% CI)	r
Lot 1	1.06 [1.01, 1.12]	0.08 [0.06, 0.11]	0.98
Lot 2	1.05 [1.00, 1.10]	0.07 [0.05, 0.09]	0.98
Lot 3	1.06 [1.01, 1.10]	0.06 [0.03, 0.07]	0.98

A user performance test was performed by a total of 187 lay users. The only instructions provided to the lay users were the device instructions for use. After reading the materials, each study subject lanced their finger and performed both a glucose test and a ketone test. Immediately after the lay users self-tested, samples were obtained by healthcare professionals and tested. The samples tested had glucose values ranging from 71 to 547 mg/dL, and ketone values ranging from 0.03 to 0.48 mmol/L. Test results comparing lay user to healthcare professionals are summarized below as linear regressions.

Glucose $y = 1.03x – 4.2$, $r = 0.98$
Ketone $y = 1.00x + 0.01$, $r = 0.96$

b. Matrix comparison:

Glucose venous, arterial and neonatal matrix comparison established in k021960.

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:

Glucose expected values were established in k021960.

In the labeling, expected blood glucose levels for people without diabetes (referenced from American Diabetes Association Standards of Care, 2008) are presented as follows:

Before eating - less than 100 mg/dL
Two hours after meals - less than 140 mg/dL

Expected levels of B-ketones for people without diabetes (referenced from Diabetes Care 1997;20:1347-5) are less than 0.6 mmol/L.

N. Instrument Name:

Precision Xceed Pro Monitor

O. System Descriptions:

1. Modes of Operation:

Each glucose and B-ketone 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, or venous, arterial or neonatal whole blood. Since the whole blood sample is applied directly to the test strip, there are no special handling or storage issues.

5. Calibration:

   Scanning the bar code label on each test strip foil packet prior to use automatically calibrates the monitor and checks the expiration date.

6. Quality Control:

   Glucose and ketone control solutions at two concentrations should be tested with this device. Acceptable ranges for each control level are printed on the respective 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.