

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

A. 510(k) Number:

k113314

B. Purpose for Submission:

New device

C. Measurand:

Capillary, Venous and Arterial whole blood glucose

D. Type of Test:

Quantitative Amperometric assay (Glucose Dehydrogenase (GDH-FAD))

E. Applicant:

HMD Biomedical, Inc.

F. Proprietary and Established Names:

Precichek NS-101 POCT Professional Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1345, Glucose, Dehydrogenase, Glucose

21 CFR § 862.1345, Glucose Test System

21 CFR 862.1660, Quality Control Material (assayed and unassayed)

2. Classification:

Class II and Class I (reserved)

3. Product code:

LFR, JJX

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indications for Use below

2. Indication(s) for use:

Precichek NS-101 POCT Professional Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips, venous whole blood and arterial whole blood samples. The Precichek NS-101 POCT Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by health care professionals in a clinical setting.

The Precichek NS-101 POCT Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a healthcare professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control.

The Precichek NS-101 POCT Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The Precichek KP Blood Glucose Test Strip is for use with the Precichek NS-101 POCT Professional Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood from the fingertips, venous and arterial whole blood samples.

The Precichek Glucose Control Solution is intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals to assess the performance of the Precichek NS-101 POCT Professional Blood Glucose monitoring system and the Precichek KP Blood Glucose Test Strips to check that meter and test strips are working together properly and that the test is performing correctly.

3. Special conditions for use statement(s):

- For in vitro diagnostic use only
- For Professional Use only
- Not intended for use on neonates
- Not for diagnosis of or screening for diabetes mellitus
- Not to be used for patients who are dehydrated, hypotensive, in shock, critically ill or in a hyperosmolar state

- Multiple-patient use meters must be disinfected between use following labeling recommendations
- Multiple patient use systems should only use single use, auto disabling lancing devices.

4. Special instrument requirements:

PreciChek NS-101 POCT Professional Blood Glucose Monitoring System

I. Device Description:

The PreciChek NS-101 POCT Professional Blood Glucose Monitoring System contains a blood glucose meter (PreciChek NS-101 POCT Professional Blood Glucose Meter), PreciChek KP Blood Glucose Test Strips, PreciChek Glucose Control Solution (Level I and Level II), and Check Strip. The Check Strip, can be used to check that the meter is operating properly. Meter contains a USB cable which is used to charge the battery of the meter but does not transfer results to a computer. Owner's booklet is provided in the kit. Single use Auto-disabling lancets are sold separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Sure Step Flexx (LifeScan, Inc.)
Sure Step Flexx Glucose Control Solution (LifeScan Inc.)
2. Predicate 510(k) number(s):
k023194
k032985
3. Comparison with predicate:

Similarities		
Item	Candidate Device PreciChek NS-101 POCT	Predicate SureStep Flexx (k023914)
Intended Use	To quantitatively measure the concentration of glucose (sugar) in capillary whole blood samples drawn from the fingertip, venous, and arterial whole blood by healthcare professionals to monitor patient's blood glucose in clinical settings. The system is used outside the body (in vitro diagnostic use)	Same

Similarities		
Item	Candidate Device Precichek NS-101 POCT	Predicate SureStep Flexx (k023914)
Code System	Bar code	Same
Blood sample source	Fresh whole blood (capillary, venous, arterial)	Same
Calibration	Plasma Equivalent	Same
Operating Procedure	Menu Control-Operational ID, Patient ID, Strip Lot	Same
Characteristics	For Professional Use Only	Same

Differences		
Item	Device	Predicate
Methodology	Glucose Dehydrogenase(GDH-FAD)	Glucose Oxidase
Principle	Electrochemical reaction	Photochemical reaction
Reaction time	5 seconds	30 seconds
Blood Glucose Range	20 - 600 mg/dl	0-500 mg/dl
Operational environment	10-40°C, 50-104°F 20-80% RH	18-30°C, 64-86°F 30-70% RH
Blood Sample Volume	0.5 µL	5µL-30µL
Power source	3.7V Li battery, rechargeable via USB	3AA 1.5v alkaline batteries

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.

ISO 14971: Medical Devices-Applications of risk management to medical devices

IEC 60601-1: Medical Electrical Equipment-Part1: General Requirements for Safety

L. Test Principle:

This test is based on electrochemical biosensor technology and the principle of capillary action. The electrical current generated by the reaction of glucose with the reagent of the strip is measured by the meter and is displayed as the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Within-day precision was performed using venous whole blood samples at five glucose concentrations, three test strip lots, and 10 Precichek NS-101 POCT meters. Each level was evaluated 10 times for a total of 100 tests per each glucose level. Day-to-day precision was evaluated using three glucose control solutions with concentration levels of low (45mg/dL), normal (100mg/dL) and high (300 mg/dL). The day-to-day precision was evaluated over a ten-day period using three test strip lots and 10 Precichek NS-101 POCT meters. A summary of the test results is presented below.

Within-day Precision (whole blood)
KPH 14081 (Lot 1)

Concentration (mg/dL) of glucose	YSI	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
10-50	40.6	100	40.7	2.0	4.8
51-110	93.3	100	100.1	4.1	4.1
111-150	120	100	124.8	3.1	2.5
151-250	213	100	215.8	7.8	3.6
251-400	336	100	340.0	12.1	3.5
401-600	532	100	537.4	14.0	2.6

KPH15112 (Lot 2)

Concentration (mg/dL) of glucose	YSI	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
10-50	40.6	100	40.5	1.7	4.2
51-110	93.3	100	96.9	3.6	3.7
111-150	120	100	122.8	3.6	3.0
151-250	213	100	206.9	7.8	3.8
251-400	336	100	322.9	9.5	3.0
401-600	532	100	522.8	16.3	3.1

KPH 14082 (Lot 3)

Concentration (mg/dL) of glucose	YSI	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
10-50	40.6	100	40.0	1.8	4.6
51-110	93.3	100	94.9	4.5	4.7
111-150	120	100	125.4	3.5	2.8
151-250	213	100	206.7	9.0	4.4

251-400	336	100	316.4	14.3	4.5
401-600	532	100	516.4	16.7	3.2

All 3 lots Combined

Concentration (mg/dL) of glucose	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
10-50	100	40.4	1.9	4.6
51-110	100	97.3	4.5	4.6
111-150	100	124.3	3.5	2.8
151-250	100	209.8	9.0	4.3
251-400	100	326.5	14.3	4.4
401-600	100	525.5	16.7	3.2

Day-to-Day Precision (control materials)

KPH 14081 (Lot 1)

Control level	YSI (mg/dL)	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level I (45 mg/dL)	50.0	100	60.3	2.7	4.5
Level II (100 mg/dL)	100	100	124.4	5.9	4.7
Level III (300 mg/dL)	300	100	433.6	15.2	3.5

KPH15112 (Lot 2)

Control level	YSI (mg/dL)	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level I (45 mg/dL)	50.0	100	61.5	2.7	4.3
Level II (100mg/dL)	100	100	122.9	5.2	4.2
Level III (300 mg/dL)	300	100	438.0	15.4	3.5

KPH 14082 (Lot 3)

Control level (mg/dL)	YSI (mg/dL)	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1 (45 mg/dL)	50.0	100	60.1	2.9	4.8
Level II (100 mg/dL)	100	100	124.2	5.3	4.2
Level III (300 mg/dL)	300	100	440.8	16.4	3.7

All 3 Lots Combined

Control level (mg/dL)	YSI (mg/dL)	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1 (45 mg/dL)	50.0	100	60.6	2.8	4.7
Level II (100 mg/dL)	100.0	100	123.8	5.5	4.4
Level III (300mg/dL)	300.0	100	437.5	15.9	3.6

b. *Linearity/assay reportable range:*

Linearity testing was evaluated using 8 levels of venous whole blood samples (18, 41, 103, 128, 200, 313 and 654 mg/dL) as measured by YSI. Measurements were taken 10 times for each concentration and the values of the Precichek NS-101 POCT meter were compared to those obtained from the YSI-2300. 3 lots of test strips were used in the linearity testing.

Linearity of Precichek NS-101 vs YSI 2300 for each test strip lot

Strip lot	Linear Regression	95% CI slope	95% CI intercept	R ²	N
1	$y = 0.98x + 0.26$	± 0.01	± 3.46	0.995	160
2	$y = 0.98x + 0.94$	± 0.01	± 3.21	0.996	160
3	$y = 0.98x + 0.79$	± 0.01	± 3.47	0.995	160
combined	$y = 0.98x + 0.66$	± 0.01	± 1.94	0.995	480

The claimed measuring range for this device is 20- 600 mg/dL

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

Traceability: The Precichek NS-101 POCT BGMS is traceable to the NIST SRM 917 reference material.

Stability: Real time stability studies were conducted to assess the shelf-life and open vial stability of the control solutions and test strips. Real time stability studies are still on-going. For controls, the sponsor claims an unopened shelf life of 18 months and stability of 90 days after opening, when stored at 50-80 °F (10-30 °C). For test strips, the sponsor claims that the unopened test strips have a 24 month shelf life and are stable for 90 days after first opening, when stored at 10-40°C (50-104° F). The sponsor's protocol and acceptance criteria were reviewed and considered acceptable.

Control Value Assignment: Previously cleared under k032985. The value assignment of the Precichek glucose control solutions were determined by in-house procedure. The control solutions were prepared by gravimetric addition of glucose to achieve target values of 45 mg/dL for Level I and 300 mg/dL for Level II. Values

were confirmed by YSI 2300 method. Verification of the control solutions were tested with 30 test strips and 5 Precichek NS-101 POCT Professional Blood Glucose Meters per level of control. The target ranges were set at the following:

Glucose Control solution	Target concentration	Acceptable Range
Level 1	45 mg/dL	35 – 65 mg/dL
Level 2	300 mg/dL	336-545 mg/dL

d. Detection limit:

The measuring range of the system is 20-600 mg/dL. This range was verified by the linearity study above (section M.1.b)

e. Analytical specificity:

Whole blood samples were spiked to nominal glucose concentrations of 90-120 mg/dL and 300-400 mg/dL. The interfering substance was prepared at 5 concentrations to include normal (therapeutic) and high (toxic). Each level was analyzed 6 times The sponsor defines no significant interference as $\leq 10\%$ difference.

Endogenous and Exogenous Substances	Highest Concentration tested showing no interference (mg/dL)
Acetaminophen	25
Bilirubin	20
Dopamine	13
Ibuprofen	40
Methyl dopa	10
Tolarzamide	10
Cholesterol	500
Creatinine	30
Ephedrine	10
L-dopa	2
Salicylate	40
Tolbutamide	12
Tetracyclin	4
Ascorbic Acid	2.25
Galactose	1000
Lactose	50
Maltose	800
D-Xylose	50

Urea	500
Glutathione	55
Triglycerides	1000
Uric Acid	15

The labeling states “A sample with large amounts of the substances such as Triglycerides (>1,000 mg/dL), ascorbic acid (>2.25mg/dL), uric acid (>15mg/dL) and xylose (>50mg/dL) may cause a higher result.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor performed accuracy studies to demonstrate the performance of the Precichek NS-101 POC meter compared to the YSI 2300 reference method. The system accuracy evaluation was performed with 105 fresh capillary blood samples (5 spiked and 5 altered), with glucose concentrations distributed over the range of 20-600 mg/dL. Samples were analyzed using 3 Precichek NS-101 POCT meters and 3 lots of test strips. To obtain the blood glucose concentrations <50 mg/dL and >500 mg/dL, samples were allowed to glycolize or were spiked to achieve desired concentrations. The results relative to YSI are summarized in the tables below.

Capillary Whole Blood:

System accuracy results for glucose concentrations <75 mg/dL

Strip Lot	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
1	9/16 (56.3%)	14/16 (87.5%)	16/16 (100.0%)
2	11/16 (68.8%)	14/16 (87.5%)	16/16 (100.0%)
3	9/16 (56.3%)	15/16 (93.8%)	16/16 (100.0%)

System accuracy results for glucose concentrations ≥ 75 mg/dL

Strip Lot	Within ±5%	Within ±10%	Within ±15%	Within ± 20%
1	40/89 (44.9%)	70/89 (78.7%)	82/89 (92.1%)	86/89 (96.6%)
2	46/89 (51.7%)	69/89 (77.5%)	81/89 (91.0%)	86/89 (96.6%)
3	46/89 (51.7%)	73/89 (82.0%)	86/89 (96.6%)	87/89 (97.8%)

Regression Analysis vs. YSI (glucose range 14.0 -617 mg/dL)

Lot Number	Slope and y-intercept	R ²	N
1	Y = 1.00x + 3.70	0.98	105
2	Y = 0.95x + 9.33	0.98	105
3	Y = 0.95x + 6.81	0.98	105

b. Matrix comparison:

The sponsor performed matrix comparison studies to demonstrate the performance of the Precichek NS-101 POC meter compared to the YSI 2300 reference method. The evaluation was performed 112 EDTA venous blood samples (5 spiked and 5 altered) and 100 EDTA arterial samples (5 spiked, 5 altered) with glucose concentrations distributed over the range of 20-600 mg/dL. Samples were analyzed using 3 Precichek NS-101 POCT meters and 3 lots of test strips. To obtain the blood glucose concentrations <50 mg/dL and >500 mg/dL, samples were allowed to glycolize or were spiked to achieve desired concentrations. The results relative to YSI are summarized in the tables below.

Venous Whole Blood:

System accuracy results for glucose concentrations <75 mg/dL

Strip Lot	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
1	9/17 (52.9%)	14/17 (82.4%)	17/17 (100.0%)
2	6/17 (35.3%)	13/17 (76.5%)	17/17 (100.0%)
3	8/17 (47.1%)	15/17 (88.2%)	17/17 (100.0%)

System accuracy results for glucose concentrations ≥ 75 mg/dL

Strip Lot	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
1	34/95 (35.8%)	66/95 (69.5%)	88/95 (92.6%)	93/95 (97.8%)
2	39/95 (41.1%)	71/95 (74.7%)	88/95 (92.6%)	93/95 (97.8%)
3	50/95 (52.6%)	80/95 (84.2%)	89/95 (93.7%)	93/95 (97.8%)

Regression Analysis vs. YSI (glucose range 14.0 -617 mg/dL)

Lot Number	Slope and y-intercept	R ²	N
1	Y = 0.95x + 0.19	0.97	112
2	Y = 0.95x + 7.44	0.97	112
3	Y = 0.98x + 6.93	0.98	112

Arterial Whole Blood:

System accuracy results for glucose concentrations <75 mg/dL

Strip Lot	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
1	9/17 (52.9%)	14/17 (82.4%)	17/17 (100%)
2	5/17 (29.4%)	13/17 (76.5%)	17/17 (100%)
3	8/17 (47.1%)	15/17 (88.2%)	17/17 (100%)

System accuracy results for glucose concentrations ≥ 75 mg/dL

Strip Lot	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
1	33/83 (40.0%)	64/83 (77.1%)	79/83 (95.2%)	81/83 (97.6%)

2	36/83 (43.4%)	60/83 (72.3%)	73/83 (88.0%)	79/83 (95.2%)
3	34/83 (41.0%)	64/83 (77.1%)	77/83 (92.8%)	81/83 (97.6%)

Regression Analysis vs. YSI (glucose range 14.0 -617 mg/dL)

Lot Number	Slope and y-intercept	R ²	N
1	$Y = 1.02x + 2.77$	0.98	100
2	$Y = 1.04x + 1.11$	0.98	100
3	$Y = 1.04x + 0.00$	0.98	100

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):*

None

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Time of day	Expected Range, Non-diabetes
Fasting and before meals	Less than 100 mg/dL
2 hours after meals	Less than 140 mg/dL

Sponsor referenced: American Diabetes, Association Position Statement, Diabetes Care Vol. 34 (Supp.1) p.S13 (2011)

N. Instrument Name:

Precicheck NS-101 POCT Professional 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 additional readings. Each test strip requires a sample volume of 0.5µL.

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device? :

Yes _____ or No ☒ _____

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?:

Yes _____ or No ☒ _____

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes ☒ _____ or No _____

The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

3. Specimen Identification:

The device has a scanner lens. When you press and hold the "Scan" button, the red LED light will be turned on to penetrate the scanner lens and read the bar coded labeled sample.

4. Specimen Sampling and Handling:

This device is intended to be used with capillary whole blood samples drawn from the fingertip, venous and arterial whole blood EDTA samples. No special handling or storage is needed.

5. Calibration:

The device is calibrated by a coding process. The code number is the last two digits of the strip lot number. The user should input the last two digits of the strip lot number into the memory before use. While performing the blood glucose test, the strip lot number printed on the vial label is scanned to match the one in the memory. The meter then applies a formula to calculate the glucose value.

6. Quality Control:

Two levels of glucose control solutions (Level 1, 2) are provided within the kit from the

sponsor. The labeling provides instructions on when to test control materials. An acceptable range for each control level is printed on the test strip vial label. If the control values fall outside these ranges, the user is referred to customer support for problems and more information.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:

1. Altitude Studies: Venous whole blood samples, with glucose concentrations, according to YSI, from 30-594 mg/dL were analyzed using 3 Precichek NS-101 POCT test strip lots and 10 Precichek NS-101 POCT meters. Results were compared to YSI values and resulted in no significant bias ($\leq 10\%$) for all samples tested. The data submitted support use of the device up to 8800 feet (2,750 meters).
2. Temperature and Humidity Studies: The sponsor performed temperature and humidity studies using venous whole blood samples at 6 glucose ranges (30-50, 51-110, 151-250, 251-400 and 401-600 mg/dL), 5 Precichek NS-101 POCT meters and 2 lots of Precichek NS-101 test strip lots. Results demonstrated that the system can be used in conditions of 50° - 104°F (10° - 40°C) with relative humidity 20-80% and stored under conditions of 50° - 104°F (10° - 40°C) and relative humidity of 20-80%. No significant effect ($\leq 10\%$ relative to YSI) was observed at the temperature and humidity combinations tested. The following combinations were tested: low temperature/low humidity, low temperature/high humidity, high temperature/low humidity and high temperature/high humidity. The results support the claims in the labeling that the system can be used in conditions of 50° - 104°F (10°-40°C) with relative humidity of 20-80%.
3. Sample Volume Studies: Sample volume studies were performed using venous whole blood samples with concentrations of 49.3, 97, 123, 210, 336, and 488 mg/dL at 10 sample volumes (0.3, 0.35, 0.4, 0.45, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0. Ten Precichek POCT meters and 2 lots of test strips were used in the study and results were compared to YSI. Results support the claimed minimum sample volume of 0.5µL.
4. Infection Control Studies: The device is intended for multi-patient use. Disinfection efficacy studies were performed on the materials comprising the meter by outside commercial testing demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant (Clorox Germicidal Wipes) (EPA Registration #67619-12). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials for the meter after 18,250 cleanings and 18,250 disinfection cycles with the Clorox Germicidal Wipes. The robustness studies were designed to simulate 5 years of multi-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.
5. Readability Study: Not applicable. This device is for “Professional Use” only.
6. Hematocrit Study: The effect of hematocrit was evaluated using whole blood samples spiked with seven hematocrit levels (25, 30, 35, 40, 45, 55, 65%) at glucose

concentrations distributed within the measuring range (20-50, 51-110, 111-150, 151-250, 251-400, and 401-600 mg/dL) of the device. Each concentration was tested in replicates of 6. The study incorporated 6 glucose meters. Blood analysis was also performed on the YSI 2300 glucose analyzer. Results of samples with hct levels between 30-55% showed bias versus the reference method of $\leq \pm 15\%$)

7. EMC Testing: The sponsor provided the appropriate documentation certifying that electromagnetic testing (EMC) had been performed and the Precichek NS-101 POCT Professional Blood Glucose Monitoring System was found compliant.

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.