

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

A. 510(k) Number:

k093475

B. Purpose for Submission:

Rebranding of a cleared device

C. Measurand:

Whole blood glucose

D. Type of Test:

Whole blood glucose concentration through a quantitative amperometric assay
(Glucose Oxidase)

E. Applicant:

Hygieia, Inc.

F. Proprietary and Established Names:

BaseSens I Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.1345, Glucose Test System
21 CFR § 862.1660, Quality Control Material (assayed and unassayed)
2. Classification:
Class II (assay) and Class I, reserved (controls)
3. Product code:
NBW, Blood Glucose Test System, Over-the-Counter
CGA, Glucose Oxidase, Glucose
JJX, Single (specified) analyte controls (assayed and unassayed)
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
See indication for use below.
2. Indication(s) for use:
The BaseSens I Blood Glucose Monitoring System is used for the quantitative measurement of glucose levels in capillary whole blood as an aid in monitoring the effectiveness of diabetes management at home or in clinical settings. The BaseSens I Blood Glucose Monitoring System should be used only for testing outside the body (in vitro diagnostic use only). The BaseSens I Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes

mellitus, and is not intended for use on neonates. Testing sites include the fingertip along with alternate sites testing (AST) on the forearm, palm, thigh and calf. AST in this system can be used only during steady-state blood glucose conditions.

BaseSens I Test Strip is used with the BaseSens I Blood Glucose Meter for quantitatively measuring glucose in capillary whole blood. The BaseSens I Test Strip is intended for self-testing outside the body (in vitro diagnostic use only). The BaseSens I Test Strips are not intended for the diagnosis of or screening for diabetes mellitus, and are not intended for use on neonates. Testing sites include the fingertip along with alternate sites testing (AST) on the forearm, palm, thigh and calf. AST in this system can be used only during steady-state blood glucose conditions.

BaseSens I Control A&B Solutions are red liquid to check that both the meters and test strips are working together properly. It contains a known range of glucose as written on the bottle.

3. Special conditions for use statement(s):

Not intended for diagnosis or screening of diabetes mellitus

- Not intended for use on neonates
- For *in vitro* diagnostic use only
- Not for use on critically ill patients, patients in shock, dehydrated patients or hyperosmolar patients
- AST in this system can be used only during steady-state blood glucose conditions

4. Special instrument requirements:

BaseSens I Blood Glucose Meter

I. Device Description:

The BaseSens I Blood Glucose Monitoring System (BGMS) is comprised of the BaseSens I Blood Glucose Meter, the BaseSens I Blood Glucose Test Strips (glucose oxidase) and the BaseSens I Control Solutions (2 levels).

The BaseSens I BGMS is identical to the CareSens N BGMS (k083468). The BaseSens I System is a rebranded CareSens N System.

J. Substantial Equivalence Information:

1. Predicate device name(s):

i-Sens CareSens BGMS
CareSens N BGMS

2. Predicate K number(s):

k080923 and k083468 respectively

3. Comparison with predicate:

Item	Proposed Device	CareSens N BGMS (k083468)	CareSens BGMS (k080923)
Similarities			
Intended Use	The BaseSens I BGMS is used for the quantitative measurement of glucose levels in capillary whole blood as an aid in monitoring the effectiveness of diabetes management at home or in clinical settings. The BaseSens I BGMS should be used only for testing outside the body (in vitro diagnostic use only). The BaseSens I BGMS is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. Testing sites include the fingertip along with alternate sites testing (AST) on the forearm, palm, thigh and calf. AST in this system can be used only during steady-state blood glucose conditions.	same	same
Enzyme	Amperometric method	same	same
Measurement Principle	Glucose oxidase (<i>A. Niger</i>)	same	same
Test Principle	Glucose oxidase chemical reaction. The instrument measures the extent of current caused by the presence of glucose in sample.	same	same
Sample	Fresh capillary whole blood	same	same
Electrode	Carbon	same	same
Calibration	Plasma-equivalent	same	same
Test time (seconds)	5	same	same
Sample volume (µl)	0.5	same	same
Memory	250	same	same
Test range (mg/dL)	20 to 600	same	same
Hematocrit range (%)	20 to 60 (below 400 mg/dL)	same	same
Glucose units	mg/dL or mmol/L (default is mg/dL)	same	same
Alternate site testing	Yes	same	same
Operating humidity	10 to 90 %	same	same
Differences			
Coding	Automatic code identification	same	Manual input
Self-diagnosis of code identification function	Yes	same	No

3 time set alarms and 2 hour post meal alarm	Yes	same	No
Post-meal flagging	Yes	same	No
Number of buttons	3	same	2 (CareSens II) 1 (CareSens POP)

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.
- IEC/EN 61601-1-2, (Second Edition, 2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests. (General)

L. Test Principle:

The BaseSens I Blood Glucose Monitoring System uses electrochemical methodologies. The system quantitatively measures blood glucose levels using an amperometric method, which involves detecting the current produced from glucose oxidation. The electrons generated during this reaction are transferred from the blood to the electrodes. The magnitude of the resultant current is proportional to the concentration of glucose in the specimen and the signal is converted into a readout displayed on the meter.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
Established in k080923 and k083468
 - b. *Linearity/assay reportable range:*
Established in k080923 and k083468
 - c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Established in k080923 and k083468
 - d. *Detection limit:*
Established in k080923 and k083468
 - e. *Analytical specificity:*
Established in k080923 and k083468
 - f. *Assay cut-off:*
Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*
Established in k080923 and k083468

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):*
Not applicable

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range:
Expected blood glucose levels for people without diabetes (referenced from *Diagnosis of Diabetes*, NIH Publication No. 05-4642, January 2005.)

Time	Range (mg/dL)	Range (mmol/L)
Fasting	70 to 110	3.9 to 6.1
One hour after meals	less than 160	less than 8.9

N. Instrument Name:

BaseSens I Blood Glucose Meter

O. Systems Descriptions:

1. Modes of Operation:

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

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

Yes _____ or No X

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

Yes _____ or No X

2. Software:
Reviewed under k080923 and k083468
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, which can be applied directly to the test strip.
5. Calibration:
The device has automatic code identification. No further calibration is required.
6. Quality Control:
The sponsor has two levels of controls available for the system (not included in the kit but available for purchase). When a test strip is inserted into the meter, each control can be measured by following the instructions for “Checking the System” provided in the Owner’s Booklet of the system. An acceptable range for each control level is printed on the test strip vial label. The user is instructed to contact the Customer Help Line during the operational times or a healthcare provider outside the operational times if the 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.