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
gingertip 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 fingertips 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:

<table>
<thead>
<tr>
<th>Item</th>
<th>Proposed Device</th>
<th>CareSens N BGMS (k083468)</th>
<th>CareSens BGMS (k080923)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Similarities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intended Use</td>
<td>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.</td>
<td>same</td>
<td>same</td>
</tr>
<tr>
<td>Enzyme</td>
<td>Amperometric method</td>
<td>same</td>
<td>same</td>
</tr>
<tr>
<td>Measurement Principle</td>
<td>Glucose oxidase (A. Niger)</td>
<td>same</td>
<td>same</td>
</tr>
<tr>
<td>Test Principle</td>
<td>Glucose oxidase chemical reaction. The instrument measures the extent of current caused by the presence of glucose in sample.</td>
<td>same</td>
<td>same</td>
</tr>
<tr>
<td>Sample</td>
<td>Fresh capillary whole blood</td>
<td>same</td>
<td>same</td>
</tr>
<tr>
<td>Electrode</td>
<td>Carbon</td>
<td>same</td>
<td>same</td>
</tr>
<tr>
<td>Calibration</td>
<td>Plasma-equivalent</td>
<td>same</td>
<td>same</td>
</tr>
<tr>
<td>Test time (seconds)</td>
<td>5</td>
<td>same</td>
<td>same</td>
</tr>
<tr>
<td>Sample volume (μl)</td>
<td>0.5</td>
<td>same</td>
<td>same</td>
</tr>
<tr>
<td>Memory</td>
<td>250</td>
<td>same</td>
<td>same</td>
</tr>
<tr>
<td>Test range (mg/dL)</td>
<td>20 to 600</td>
<td>same</td>
<td>same</td>
</tr>
<tr>
<td>Hematocrit range (%)</td>
<td>20 to 60 (below 400 mg/dL)</td>
<td>same</td>
<td>same</td>
</tr>
<tr>
<td>Glucose units</td>
<td>mg/dL or mmol/L (default is mg/dL)</td>
<td>same</td>
<td>same</td>
</tr>
<tr>
<td>Alternate site testing</td>
<td>Yes</td>
<td>same</td>
<td>same</td>
</tr>
<tr>
<td>Operating humidity</td>
<td>10 to 90 %</td>
<td>same</td>
<td>same</td>
</tr>
<tr>
<td><strong>Differences</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coding</td>
<td>Automatic code identification</td>
<td>same</td>
<td>Manual input</td>
</tr>
<tr>
<td>Self-diagnosis of code identification function</td>
<td>Yes</td>
<td>same</td>
<td>No</td>
</tr>
</tbody>
</table>
3 time set alarms and 2 hour post meal alarm

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>same</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-meal flagging</td>
<td>Yes</td>
<td>same</td>
<td>No</td>
</tr>
<tr>
<td>Number of buttons</td>
<td>3</td>
<td>same</td>
<td>2 (CareSens II)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 (CareSens POP)</td>
</tr>
</tbody>
</table>

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

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.*)

<table>
<thead>
<tr>
<th>Time</th>
<th>Range (mg/dL)</th>
<th>Range (mmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting</td>
<td>70 to 110</td>
<td>3.9 to 6.1</td>
</tr>
<tr>
<td>One hour after meals</td>
<td>less than 160</td>
<td>less than 8.9</td>
</tr>
</tbody>
</table>

**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.