510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I  Background Information:

A  510(k) Number

K190225

B  Applicant

Seventh Sense Biosystems, Inc.

C  Proprietary and Established Names

TAP Blood Collection® Device

D  Regulatory Information

<table>
<thead>
<tr>
<th>Product Code(s)</th>
<th>Classification</th>
<th>Regulation Section</th>
<th>Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRJ</td>
<td>Class II</td>
<td>21 CFR 862.1675 -</td>
<td>CH - Clinical</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Blood Specimen</td>
<td>Chemistry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Collection Device</td>
<td></td>
</tr>
</tbody>
</table>

II  Submission/Device Overview:

A  Purpose for Submission:

To request a modification to the indications for use to include layperson self-administration of TAP Blood Collection Device to obtain capillary whole blood from the upper arm.

B  Measurand:

Not applicable – blood collection system.

C  Type of Test:

Not applicable.
III  Intended Use/Indications for Use:

A  Intended Use(s):

See Indications for Use below.

B  Indication(s) for Use:

The TAP Blood Collection® Device is a lithium heparin coated single use device intended to be used to collect capillary blood from the upper arm of adults (21 years of age or older). The TAP Blood Collection Device is for measurement of HbA1c on blood specimens which can be collected by self-administration of the TAP Device by a layperson or by a healthcare worker in a healthcare setting. The collected sample is then transported for analysis in a clinical laboratory for determination of Hemoglobin Alc (HbA1c) using tests intended for monitoring glycemic control.

C  Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

After sample collection with the first collection unit, repeat sample collection with a collection unit. If the collection unit fill indicator window does not turn completely red after 10 minutes, remove the device, replace the gray protector, and the device should be handed to the healthcare worker.

Select an area on the upper arm that is clear of visible hair. If a suitable site cannot be identified, shave the sampling site.

Do not use on injured skin (broken, swollen, rash).

Do not use on individuals with known allergies to stainless steel.

D  Special Instrument Requirements:

Not applicable.

IV  Device/System Characteristics:

A  Device Description:

The TAP Blood Collection® Device (herein “TAP Device”) is a single use, sterilized whole blood specimen collection and transportation device that uses a combination of two mechanisms, capillary action and vacuum extraction, to obtain a capillary blood sample from the upper arm. The device consists of an integrated reservoir with a visual fill indicator window. The device is designed to collect and contain approximately 100 µL of capillary whole blood. The internal
fluid path is coated with 100 units of dry lithium heparin. The top of the device includes a green button and a fill indicator window. The base of the device includes a release liner that covers a layer of hydrogel adhesive. The hydrogel adhesive seals to the skin and holds the device in place during use. The TAP device contains an array of microneedles in order to puncture through the skin. The microneedles are activated by a spring, released by pushing the green button. The device is provided sterile in a tray and foil pouch. Instructions on how to collect the capillary sample are provided in the package insert for healthcare workers.

B Principle of Operation:

The TAP Blood Collection® Device has a mechanism for skin puncture, a mechanism for drawing blood, an anticoagulant, and can be used for temporary storage of blood (up to six hours).

The device uses microneedles to create skin punctures for the collection of capillary blood. When actuated, the device collects the sample in an integrated reservoir, and provides an indicator to confirm that collection is complete. The device contains lithium heparin as a blood anticoagulant. The TAP Device is designed for one-time sample extraction and sample can be removed from the TAP sample access port using a pipette.

V Substantial Equivalence Information:

A Predicate Device Name(s):

TAP Blood Collection Device

B Predicate 510(k) Number(s):

K161521

C Comparison with Predicate(s):

<table>
<thead>
<tr>
<th>Device &amp; Predicate Device(s):</th>
<th>K190225</th>
<th>K161521</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Trade Name</td>
<td>TAP Blood Collection® Device</td>
<td>TAP Blood Collection® Device</td>
</tr>
<tr>
<td>General Device Characteristic Similarities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intended Use/Indications For Use</td>
<td>Device is intended for use as a blood specimen collection device</td>
<td>Same</td>
</tr>
<tr>
<td>Collection Method</td>
<td>Blood access via microneedles</td>
<td>Same</td>
</tr>
<tr>
<td>Mechanism of Blood Draw</td>
<td>Sample obtained by capillary action and vacuum</td>
<td>Same</td>
</tr>
</tbody>
</table>
## Device & Predicate

<table>
<thead>
<tr>
<th>Device(s):</th>
<th>K190225</th>
<th>K161521</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Type</td>
<td>Capillary whole blood</td>
<td>Same</td>
</tr>
<tr>
<td>Puncture Site</td>
<td>Upper arm</td>
<td>Same</td>
</tr>
</tbody>
</table>

### General Device Characteristic Differences

| Indicated User         | Layperson or healthcare worker | Healthcare worker |

## Standards/Guidance Documents Referenced:

- CLSI EP15-A3 User Verification of Precision and Estimation of Bias; Approved Guideline
- ISO 10993-5 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity

## Performance Characteristics (if/when applicable):

### A Analytical Performance:

1. **Precision/Reproducibility:**

   To demonstrate lay user intra-operator precision, each participant self-collected up to three samples using TAP Devices from the same production lot. All collected samples were transferred to the laboratory and tested for HbA1c using an FDA cleared HbA1c test system. Participants for whom at least two TAP Device HbA1c results were collected were included in the analysis (N = 100). Intra-operator precision analysis was based on recommendations in CLSI EP15-A3 for unbalanced design, stratified between groups with participant HbA1c averages at or below 7%, and those with HbA1c averages above 7.5%. The analysis determined the intra-operator coefficient of variation (%CV). The results of the intra-operator precision study are shown below.

<table>
<thead>
<tr>
<th>N</th>
<th>Average HbA1c</th>
<th>Min HbA1c</th>
<th>Max HbA1c</th>
<th>Within operator %CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>59</td>
<td>5.8</td>
<td>4.7</td>
<td>6.9</td>
<td>1.06%</td>
</tr>
<tr>
<td>41</td>
<td>8.6</td>
<td>7.0</td>
<td>13.3</td>
<td>0.91%</td>
</tr>
</tbody>
</table>

2. **Linearity:**

   Not applicable.

3. **Analytical Specificity/Interference:**

   Not applicable.
4. Assay Reportable Range:

Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The shelf-life stability study protocols and acceptance criteria of the TAP Device were reviewed and found to be acceptable. Currently, the real-time stability testing supports a 6-month shelf life when stored at 18-28°C with ongoing studies to support up to 12-month expiration dating.

Additional testing evaluated on the candidate device:

The sponsor conducted additional studies to assess TAP device malfunction rates, sample volume, sample collection time, and sample hemolysis when sample collection was performed by lay users. Results for these studies were reviewed and found to be acceptable.

6. Detection Limit:

Not applicable.

7. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

A total of 104 adult study participants, representing both healthy (non-diabetic) and diabetic populations from a variety of educational backgrounds, races, and ethnicities were included in the method comparison study. Each participant self-collected a blood sample with the TAP Device and a healthcare professional collected one venipuncture sample from each participant. All TAP Device and venous blood samples were tested within 6 hours of the draw using an FDA cleared HbA1c test system for the method comparison analysis. The HbA1c test results from venous blood sample was compared to results obtained from the TAP Device blood collection.

A regression analysis was performed using the Passing-Bablok regression. The results are summarized in the following table:

<table>
<thead>
<tr>
<th>N</th>
<th>Slope</th>
<th>95% CI for Slope</th>
<th>Intercept</th>
<th>95% CI for Intercept</th>
<th>HbA1c range (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>91</td>
<td>1.0</td>
<td>(1.0, 1.0)</td>
<td>0.0</td>
<td>(0.0, 0.0)</td>
<td>(4.7, 13.3)</td>
</tr>
</tbody>
</table>

The resulting linear regression analysis was used to calculate the systematic difference at theoretical HbA1c values of 5.0%, 6.5%, and 12.0%. The results showed minimal bias between the TAP and venipuncture HbA1c test results across the range of HbA1c values.
An additional study was performed to assess if lay user individuals can successfully use the TAP Device to self-collect blood samples for HbA1c testing using the instructions for use. Results of the lay user study indicated 90% of the 40 participants in the lay user study successfully self-collected a capillary blood sample of sufficient quality by following the directions included with the TAP device.

2. **Matrix Comparison:**

   Not applicable. The TAP device is intended for the collection of lithium heparinized capillary whole blood only.

**C Clinical Studies:**

1. **Clinical Sensitivity:**

   Not applicable.

2. **Clinical Specificity:**

   Not applicable.

3. **Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):**

   Not applicable.

**D Clinical Cut-Off:**

Not applicable.

**E Expected Values/Reference Range:**

Not applicable.

**VIII Proposed Labeling:**

The labeling supports the finding of substantial equivalence for this device.

**IX Conclusion:**

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