510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k161521

B. Purpose for Submission:

New device

C. Measurand:

Not applicable - blood collection system

D. Type of Test:

Not applicable

E. Applicant:

Seventh Sense Biosystems, Inc.

F. Proprietary and Established Names:

TAP Blood Collection Device

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1675 Blood Specimen Collection Device

2. Classification:

   Class II

3. Product code:

   PRJ

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indications for use statement below.

2. 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 and older) by a healthcare worker. The collected sample is then transported for analysis in a clinical laboratory for the determination of Hemoglobin A1c (HbA1c) using tests intended for monitoring glycemic control.

3. Special conditions for use statement(s):

   For prescription use only.

   If the TAP Device fill indicator window does not turn completely red after 7 minutes, remove the device and repeat the collection process with a new TAP Device. If unable to collect a sample after a second attempt, seek an alternative blood collection method.

   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 locations presenting edema, abnormal skin integrity, or atypical skin health.

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

4. Special instrument requirements:

   Not applicable

I. Device Description:

The TAP Blood Collection Device is a single-use, sterilized blood collection and transportation device that uses a combination of two mechanisms, capillary action and vacuum extraction. 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.

After blood collection (must be done within 7 minutes), the TAP device is intended to be placed inside the tray that it comes with, properly sealed and labelled, and transport to a clinical laboratory for HbA1c analysis within 6 hours of post-collection, or tested in the time indicated by the A1c test system package insert. The TAP sample extraction instructions are also provided in the package insert.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   BD Vacutainer Plus PST II Tube

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

   k022130

3. Comparison with predicate:

Similarities		
Item	Candidate Device Seventh Sense Biosystems TAP Blood Collection Device	Predicate Device BD Vacutainer Plus PST II Tube (k022130)
Intended Use	Device is indicated for use as a blood specimen collection device	Same
Number of Uses	Single use disposable	Same
Anticoagulant	Available with lithium heparin	Same
Intended User	Healthcare worker, prescription use	Same
Sterility	Provided sterile	Same

Differences		
Item	Candidate Device Seventh Sense Biosystems TAP Blood Collection Device	Predicate Device BD Vacutainer Plus PST II Tube (k022130)
Collection Method	Blood access via microneedles	Venipuncture needle
Mechanism of Blood Draw	Sample obtained by capillary action and vacuum	Vacuum
Sample type	Capillary whole blood	Venous whole blood
Puncture site	Upper Arm	Multiple sites
Sample size	Up to 100µl	Up to 3 mL
Specimen container	Drawn blood stored in plastic internal chamber	Plastic tube
Storage	18-28°C (64-82°F)	4-25°C (39-77°F)

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

CLSI EP05-A3, Evaluation of Quantitative Measurement Procedures; Approved Guideline-Third Edition.

CLSI EP09-A2, Method comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition.

ISO 10993-5 Biological Evaluation of Medical Devices; Part 5: Test for in vitro cytotoxicity

ISO 10993-10 Sterilization of Health Care Products-Radiation-Part 10: Test for irritation and skin sensitivity

ISO 10993-11 Sterilization of Health Care Products-Radiation-Part 11: Tests for Systematic Toxicity.

AAMI/ANSI/ISO 11137-1:2006 Sterilization of Health Care Products-Radiation-Part 1: Requirements for Development, validation and routine control of a sterilization process for medical devices.

AAMI/ANSI/ISO 11137-2:2009 Sterilization of Health Care Products-Radiation-Part 2: Establishing the Sterilization Dose.

AAMI/ANSI/ISO 11737-3-2012 Sterilization of Health Care Products-Radiation-Part 3: Guidance on dosimetric aspects.

L. Test Principle:

The TAP Device is intended to collect capillary blood from the upper arm of adults (21 years of age and older) by a healthcare worker for HbA1c testing on compatible test systems. 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.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Lot-to-lot repeatability and inter-operator variability studies were conducted at three hospital sites. To evaluate lot-to-lot repeatability, one phlebotomist at each site collected three TAP Device samples from a minimum of 20 participants. Each of the three samples was collected using a separate TAP Device lot, for a total of three device lots used at each site. The collected samples were transferred to the laboratory at room temperature (15-30^{o}C) and tested for HbA1c using a FDA cleared HbA1c test system within 6 hours of the blood collection. The blood extraction from the TAP Device and the HbA1c testing was performed by laboratory technologists. The lot-to-lot imprecision results were similar for each of the three test sites. The within lot imprecision for the three sites ranged from 0.87% to 2.09 % CV, the between lot imprecision ranged from 0.0% to 0.89 % CV, and the total imprecision ranged from 1.20% to 2.09% CV. The combined site lot-to-lot imprecision results are summarized in the following table:

Lot-to-Lot Combined Site Results (72 subjects, 200 TAP collections)

Mean % HbA1c	Within-Lot %CV with (95% CI)	Between-Lot %CV with (95% CI)	Total %CV with (95% CI)
5.94	1.82 (1.61; 2.09)	0.0*	1.82 (1.62; 2.09)
8.43	1.16 (1.00; 1.39)	0.59 (0.38; 1.31)	1.30 (1.13; 1.55)

* Confidence Interval (CI) was not calculated because of small value of imprecision component

To evaluate inter-operator precision, three phlebotomists at each site collected a TAP Device sample from a minimum of 20 participants using one TAP Device lot. The collected samples were transferred to the laboratory at room temperature (15-30^{o}C). The blood extraction from the TAP Device and the HbA1c testing was performed by laboratory technologists. HbA1c was measured using a FDA cleared HbA1c test system within 6 hours of the blood collection. The inter-operator imprecision results were similar for each of the three test sites. The within operator imprecision for the three sites ranged from 1.22% to 1.73% CV, the between operator imprecision ranged from 0.0% to 0.94% CV, and the total imprecision ranged from 1.44% to 1.73% CV. The combined site inter-operator imprecision results are summarized in the following table:

Inter-Operator Combined Site Results (67 subjects, 195 TAP collections)

Mean % HbA1c	Within-Lot %CV with (95% CI)	Between-Lot %CV with (95% CI)	Total %CV with (95% CI)
5.94	1.59 (1.39; 1.86)	0.0*	1.59 (1.40; 1.85)
8.77	1.35 (1.18; 1.60)	0.39 (0.26; 0.73)	1.41 (1.23; 1.65)

* Confidence Interval (CI) was not calculated because of small value of imprecision component

b. Linearity/assay reportable range:

Not applicable.

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

Shelf-life Stability Study:
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^{o}C with on-going studies to support up to 12 month expiration dating.

Shipping Stability Study:
A stability study was conducted to assess the performance of the TAP Device to collect quality samples after undergoing simulated extreme shipping conditions (extreme cold, extreme heat, extreme humidity). The shipping stability study protocols and acceptance criteria of the TAP Blood Collection Device were reviewed and found to be acceptable. The study results support the manufacturer's claim the TAP Device can perform as indicated following shipping of the packaged devices.

Analyte Stability Study:
A stability study was performed to assess the stability of blood collected by the TAP Device for the measurement of HbA1c. The analyte stability study protocols and acceptance criteria of the TAP blood collection device were reviewed and found to be acceptable. The analyte stability study results support the sponsor's claim that blood may be stored within the TAP device prior to HbA1c testing for up to 6 hours, or for as long as recommended by the HbA1c test system manufacturer, whichever is less.

Additional bench testing evaluated on the candidate device:

Additional studies were conducted to assess draw volume, sample collection time, sample quality (hemolysis and blood clot formation) and device malfunction rate. Study protocols, acceptance criteria and results for these studies were provided and found to be acceptable.

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*

Not applicable.

f. *Assay cut-off:*

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was performed at three hospital clinic sites to compare %HbA1c results from blood collected using the TAP device with the HbA1c results from blood collected by venipuncture with BD Vacutainer Plus PST II Tubes with lithium heparin. A total of 243 blood sample pairs were collected by phlebotomists. The blood was extracted from the device and tested for %HbA1c by laboratory technologists at each clinic site. The measurement of %HbA1c was performed using two FDA cleared HbA1c test systems at each of the three sites. The method comparison results for each test system are summarized below:

HbA1c Test System One Regression by Site and by Combined Sites

Site	N	Slope	Slope 95% CI	Intercept	Intercept 95% CI	R	%HbA1c test range
1	43	1.025	(0.993,1.058)	-0.19	(-0.43, 0.05)	0.995	4.8-11.6
2	36	0.984	(0.939,1.028)	0.05	(-0.26, 0.36)	0.992	4.7-10.6
3	43	1.028	(1.003, 1.054)	-0.20	(-.04, -0.01)	0.997	5.2-13.6
all	122	1.021	(1.003,1.039)	-0.17	(-0.30, -0.04)	0.995	4.7-13.6

HbA1c Test System Two Regression by Site and by Combined Sites

Site	N	Slope	Slope 95% CI	Intercept	Intercept 95% CI	R	%HbA1c test range
1	43	1.002	(0.974,1.030)	0.01	(-0.20, 0.21)	0.996	4.8-11.6
2	35	0.988	(0.933,1.043)	0.05	(-0.31, 0.41)	0.988	4.7-10.6
3	43	1.053	(1.009, 1.098)	-0.34	(-.66, -0.01)	0.991	5.2-13.6
all	121	1.024	(1.001,1.047)	-0.15	(-0.32, -0.01)	0.993	4.7-13.6

The collection site on each of the subjects' upper arm area was assessed to determine if the TAP Device caused any adverse dermal responses immediately following collection, twenty minutes after collection, and seven days after collection. The assessment showed that no severe adverse effects were observed.

b. Matrix comparison:

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

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:

Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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