



Food and Drug Administration
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SEVENTH SENSE BIOSYSTEMS, INC.
C/O SHARON TIMBERLAKE
SHARON TIMBERLAKE CONSULTING LLC
27 DUNELM ROAD
BEDFORD MA 01730

February 16, 2017

Re: K161521
Trade/Device Name: TAP Blood Collection® Device
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: II
Product Code: PRJ
Dated: January 10, 2017
Received: January 17, 2017

Dear Sharon Timberlake:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Katherine Serrano -S

FOR: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K161521

Device Name

The TAP Blood Collection® Device

Indications for Use (Describe)

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

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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**510(k) Summary
for K161521
TAP Blood Collection[®] Device**

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92

1. DATE PREPARED: February 14, 2017

2. SPONSOR

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3. OFFICIAL CORRESPONDENT

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4. DEVICE INFORMATION

Proprietary Name: TAP Blood Collection[®] Device
Common Name: Blood Collection System
Classification Name: Blood Specimen Collection Device (21 CFR 862.1675)
Product Code: PRJ
Device Class: II
Panel: Chemistry (75)

5. PREDICATE DEVICE

The BD Vacutainer[®] Plus PST II[™] Tube (K022130)

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

7. 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 contains lithium heparin as an anticoagulant.

The device is intended for use by a healthcare worker. When the TAP Device is actuated, it collects the sample in an integrated reservoir and provides a visual indicator (fill indicator window) to the end user to confirm that the collection is complete and sufficient blood has been collected to conduct HbA1c testing. The sample collection time is 7 minutes or less and typically takes 2-3 minutes. The TAP Device is then sent to the laboratory for testing. The sample must be tested within 6 hours from time of collection or as indicated in the HbA1c test system package insert (whichever is less).

8. STANDARDS/GUIDANCE DOCUMENTS REFERENCED

- ANSI/AAMI/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.
- ANSI/AAMI/ISO 11137-2:2009. Sterilization of Health Care Products-Radiation - Part 2: Establishing the sterilization dose.
- ANSI/AAMI/ISO 11137-3:2012. Sterilization of Health Care Products-Radiation - Part 3: Guidance on dosimetric aspects.
- ISO 10993-5, 2009. Biological Evaluation of Medical Devices-Part 5: Test for invitro cytotoxicity.
- ISO 10993-10, 2010. Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Delay-type Hypersensitivity.
- ISO 10993-10, 2010. Biological Evaluation of Medical Devices-Part 10: Test for Irritation and Skin Sensitization.
- ISO 10993-11, 2006. Biological Evaluation of Medical Devices-Part 11: Biological Evaluation of Medical Devices-Part 11: Test for Pyrogenicity.

- ISO 10993-11, 2006. Biological Evaluation of Medical Devices-Part 11: Test for Systemic Toxicity.
- ISO 10993-4, 2002. Biological Evaluation of Medical Devices-Part 4: Selection of Test for Interactions with Blood, amended 2006.
- ASTM F1980-07, Standard Guide for Accelerated Aging of Sterile Medical Device Packages.
- Package Integrity per ASTM F1886, Standard Test Method for Seal Strength of Flexible Barrier Materials.
- Pouch Leak test per ASTM F2096, Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test).
- Pouch Seal Strength test per ASTM F88, Standard Test Method for Seal Strength of Flexible Barrier Materials.
- CLSI EP05-A3. Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-3rd Edition.
- CLSI EP09-A2-IR Method Comparison and Bias Estimation Using Patient Samples.
- Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition (Interim Revision).

9. TECHNOLOGICAL CHARACTERISTICS

Seventh Sense has identified the BD Vacutainer Plus PST II Tube (herein “Vacutainer Tube”) to support substantial equivalence to the TAP Device. Based on the information presented in Table 1, Seventh Sense believes the TAP Device is substantially equivalent in design, function, and intended use to this predicate.

Table 1: Comparison of New Device with Predicate Device

	TAP Blood Collection[®] Device	The BD Vacutainer[®] Plus PST II[™] Tube (Predicate)
Manufacturer	Seventh Sense Biosystems, Inc.	Becton Dickinson
510(k) Number	K161521	K022130
Indications for Use Statement	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) by a healthcare worker.	The BD Vacutainer [®] Plus PST II [™] Tube is a lithium heparin coated plastic evacuated blood collection tube that provides a means of collecting, transporting and processing blood in a closed tube. Blood collected in a

	TAP Blood Collection[®] Device	The BD Vacutainer[®] Plus PST II[™] Tube (Predicate)
	The collected sample is then transported for analysis in a clinical laboratory for determination of Hemoglobin A1c (HbA1c) using tests intended for monitoring glycemic control.	Vacutainer [®] Plus PST II [™] Tube is used for clinical laboratory assays involving the use of patient plasma.
Intended User	Prescription Use Device Used by Healthcare Worker	Prescription Use Device Used by Healthcare Worker
Specimen Container Capacity	100 µL	3 mL
Blood Container Material	Plastic	Plastic
Additive	Lithium Heparin	Lithium Heparin
Number of Uses	Single Use	Single Use
Sterile Device	Yes	Yes
Device Storage	18-28°C (64-82 °F)	4-25°C (39-77°F)
Sample Type Collected	Capillary Whole blood	Venous Whole Blood
Puncture Site	Upper Arm	Multiple Sites
Mechanism of Blood Draw	Vacuum	Vacuum
Collection Method	Microneedles	Venipuncture Needle (sold separately)

10. PERFORMANCE DATA

Bench Testing

Shelf-life stability, package integrity, and ship testing of the TAP Device have been performed with passing results. Heparin potency studies were also conducted to support the TAP Device's specifications for lithium heparin. The testing confirms that the TAP Device is stable and fully functional for its intended use.

Clinical Testing

Multiple clinical studies were conducted to establish the safety and effectiveness profile of the TAP Device. A description of the clinical testing is provided below.

Pivotal Study

A prospective pivotal study was conducted at multiple sites to demonstrate the overall performance of the TAP Device. A total of 143 participants were enrolled in the study, spanning representative age, gender, ethnicity, race, and health status (healthy/non-diabetic and diabetic) populations. Each participant underwent a TAP Device sample collection as well as a venipuncture collection. Samples were then analyzed within 6 hours of collection. The results of the pivotal study include:

- A method comparison was conducted at three hospital clinic sites by healthcare workers to establish equivalency of the TAP Device by comparing HbA1c levels in blood samples collected using the TAP Device with HbA1c levels in blood samples collected by venipuncture. Accuracy of the method comparison demonstrated that the HbA1c results from the TAP Device blood samples are equivalent to those from venipuncture blood samples. The mean percentage bias observed between the methods was -0.1% with a 95% Confidence Interval of (-0.4%, 0.2%). In addition, the correlation coefficient (r^2) of 0.9878 that was observed indicates there are no significant differences between the matrices when used for HbA1c testing. A detailed summary of the method comparison results for two different HbA1c analyzers used at each site is included in the following table:

Site	Analyzer	N	Slope est.	95% CI for Slope	Intercept est.	95% CI for Intercept	Corr.
1	one	43	1.025	(0.993, 1.058)	-0.19	(-0.43, 0.05)	0.995
2	one	36	0.984	(0.939, 1.028)	0.05	(-0.26, 0.36)	0.992
3	one	43	1.028	(1.003, 1.054)	-0.20	(-0.40, -0.01)	0.997
Combined	one	122	1.021	(1.003, 1.039)	-0.17	(-0.30, -0.04)	0.995
1	two	43	1.002	(0.974, 1.030)	0.01	(-0.20, 0.21)	0.996
2	two	35	0.988	(0.933, 1.043)	0.05	(-0.31, 0.41)	0.988
3	two	43	1.053	(1.009, 1.098)	-0.34	(-0.66, -0.01)	0.991
Combined	two	121	1.024	(1.001, 1.047)	-0.15	(-0.32, 0.01)	0.993

- Lot-to-lot variability testing was performed at three hospital clinic sites by healthcare workers. Lot-to-lot variability was evaluated by comparing HbA1c levels in TAP Device blood samples collected by the same operator on the same subject at each site using three different production lots. SD and %CV calculations across the HbA1c test results at each site and for the three sites combined confirm that there is no significant difference in HbA1c test results from samples collected with the different TAP Device production lots. 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 (72 subjects, 200 TAP collections):

Mean % HbA1c	Variance Component	Mean CV (%)	95% Lower Confidence Limit (%)	95% Upper Confidence Limit (%)
5.94	Within Lot	1.82	1.61	2.09
	Between Lot	0.0	N/A	N/A
	Total	1.82	1.62	2.09
8.43	Within Lot	1.16	1.00	1.39
	Between Lot	0.59	0.38	1.31
	Total	1.30	1.13	1.55

- Inter-operator variability was evaluated at three hospital clinic sites by healthcare workers. Three different operators at each site collected TAP Device blood samples from the same subject using the same TAP Device production lot and then the HbA1c levels across the three operators were compared. SD and %CV calculations across the HbA1c test results at each site and for the three sites combined confirm that there is no significant difference in HbA1c test results from samples collected by the different TAP Device operators. 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 (67 subjects, 195 TAP collections):

Mean % HbA1c	Variance Component	Mean CV (%)	95% Lower Confidence Limit (%)	95% Upper Confidence Limit (%)
5.94	Within Operator	1.59	1.39	1.86
	Between Operator	0.0	N/A	N/A
	Total	1.59	1.40	1.85
8.77	Within Operator	1.35	1.18	1.60
	Between Operator	0.39	0.26	0.73
	Total	1.41	1.23	1.65

- Safety of the TAP Device was demonstrated as the result of no significant adverse events reported throughout the study. Minimal dermal responses were observed (e.g., erythema, edema) and expected skin irritation was reported because of using the TAP Device, none of which was clinically significant. Study participants' Wong-Baker Pain Rating Scale survey results showed that pain from the TAP Device collection was significantly less than pain from venipuncture collection.

Analyte Stability Study

A prospective study was conducted to confirm the stability of the TAP Device sample for HbA1c testing according to its labeling. In this study, multiple TAP Device samples were collected and then analyzed at various time points to demonstrate that similar HbA1c results can be obtained within 6 hours of collection. A total of two or three samples were tested from each participant. All samples were measured for HbA1c in duplicate using an FDA cleared HbA1c analyzer. The average TAP percent differences in HbA1c measured after 3 hours (0.4%) and 6 hours (-1.5%) support the recommendation that blood samples collected with the TAP Devices can be analyzed for HbA1c within 6 hours.

Usability Study

The usability of the TAP Device was assessed in a prospective study. The objective of the study was to demonstrate adequate label comprehension and correct TAP Device use from the intended users of the product. The study was conducted in two phases: 1) TAP Device actuation (by pushing the green activation button) and blood collection and 2) TAP Device extraction. All participants used the TAP Device according to the written instructions. Upon completion, the participants were given a survey to assess the usability of the TAP Device. The survey responses obtained demonstrated that 95.5% of the respondents agreed that the TAP Device actuation and collection procedure was easy to execute with the provided instructions for use. The survey responses obtained demonstrated that 92.5% of respondents agreed that the TAP Device extraction procedure was easy to execute with the provided instructions. The results of the study demonstrated the TAP Device was easy to use by healthcare workers with the provided instructions.

Sample Quality Studies

The sample collection time of the TAP Device was measured in three studies. The mean collection time of 209 TAP Devices was 3 minutes and 21 seconds. The sample volume yielded was also assessed by measuring the amount of blood extracted from the device. The mean blood volume extracted from the TAP Devices was 104.6 µl.

Clotting in the TAP Device samples was visually assessed in the three studies. In two of these studies, the TAP Devices were allowed to sit for various periods of time prior to sample extraction and clotting inspection, up to 6 hours and 5 minutes. The results of these three studies showed that in 209 samples, a single small clot was observed in 19 of the samples (9%) and have been shown not to have an effect on HbA1c determinations.

Hemolysis was assessed in one study by measuring free plasma hemoglobin in collected TAP Device samples using the Hemocue Plasma/Low Hb meter. Following collection, the TAP Devices sat for various periods of time prior to sample extraction, processing, and testing, up to 6 hours and 5 minutes. The results of the study showed an average free plasma hemoglobin of 102.5 mg/dL for 69 TAP Device blood samples tested and had no effect on HbA1c determinations.

Biocompatibility and Sterility Studies

The TAP Device underwent a biocompatibility and sterility evaluation by third party testing and the device was found to be compliant.

11. STATEMENT OF SAFETY AND EFFECTIVENESS

The TAP Device design, function, and intended use is as safe and effective as the predicate device for collecting a blood sample that is used for determination of Hemoglobin A1c (HbA1c). The data presented in this 510(k) Premarket Notification further supports this conclusion. Therefore, the TAP Device is substantially equivalent to the predicate device.