November 5, 2019

Seventh Sense Biosystems, Inc.
Tim Richards
Chief Operating Officer
200 Boston Avenue, Suite 3700
Medford, MA 02155

Re: K190225
Trade/Device Name: TAP Blood Collection® Device
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: PRJ
Dated: September 26, 2019
Received: September 27, 2019

Dear Tim Richards:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm, Ph.D.
Acting Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190225

Device Name
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). The TAP Blood Collection® Device is for measurement of HbAlc 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.

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.

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5.0 510(K) SUMMARY – K190225

Submitted by:	**Seventh Sense Biosystems, Inc.** 200 Boston Avenue, Suite 3700 Medford, MA 02155 **Phone**: (617) 547-7246 **Contact**: Tim Richards
Date of Summary:	November 4, 2019
Device Trade Name:	TAP Blood Collection® Device
Common or Usual Name:	Blood Specimen Collection Device
Regulation Number:	21 CFR 862.1675
Device Class:	II
Product Code:	PRJ
Panel:	Clinical Chemistry
Predicate Device:	TAP Blood Collection® Device (K161521)
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 self-administration by a layperson or 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).
Intended Use:	Intended for use as a blood specimen collection device.

Indications 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 A1c (HbA1c) using tests intended for monitoring glycemic control.

5.1. Technological Characteristics / Substantial Equivalence

The candidate TAP Device is substantially equivalent in design, function, and intended use to the predicate TAP Device, based on the information presented in the table below. Additional detailed information is provided in Section 12.0 - Substantial Equivalence Discussion.

Characteristic	Candidate Device TAP Blood Collection Device	Predicate Device TAP Blood Collection Device (K161521)
Similarities		
Intended Use	Device is intended for use as a blood specimen collection device	Same
Prescription Use	Yes	Same
Number of Uses	Single use / Disposable	Same
Anticoagulant	Available with lithium heparin	Same
Sterility	Provided Sterile by gamma radiation; SAL of 10^{-6}	Same
Collection Method	Blood access via microneedles	Same
Mechanism of Blood Draw	Sample obtained by capillary action and vacuum	Same
Sample Type	Capillary whole blood	Same
Puncture Site	Upper Arm	Same
Sample Size	Up to 100 µL	Same
Specimen Container	Drawn blood stored in plastic internal chamber	Same
Storage	18-28°C (64-82°F)	Same
Differences		
Indicated User	Layperson or Healthcare worker	Healthcare worker

5.2. Performance Data

The purpose of this submission is to request a change in indications to add layperson use for the collection of the capillary blood sample.

Seventh Sense previously conducted bench studies to confirm the overall functional performance of the TAP Device against its design specifications and intended use as part of the original (predicate) TAP Device Premarket Notification (K161521). The previous performance testing remains valid as those studies are independent of the user and were specific to the design and functional performance requirements of the TAP Device.

In addition, Seventh Sense previously evaluated product performance attributes by conducting extensive clinical studies to confirm the overall functional performance of the TAP Device against its design specifications and intended use. These studies, detailed in the Premarket Notification for K161521, were conducted to support the design and functional properties of the TAP Device and remain valid for the candidate TAP Device.

The following additional testing was conducted in support of the proposed change in indications:

- Usability testing to demonstrate that laypeople can successfully use the TAP Device to self-collect a blood sample according to the product's written instructions for use.
- Analytical performance testing to confirm a blood sample collected by the layperson is adequate for HbA1c testing in a clinical laboratory. This study includes matrix comparison of TAP Device samples that are self-collected by laypeople compared to venous blood samples collected by a healthcare worker as well as evaluation of intra-operator repeatability (precision).

Performance Data Conclusions

The usability study demonstrated that laypeople can successfully use the TAP Device to self-collect a blood sample according to the TAP Device written instructions for use.

The analytical performance testing demonstrated that self-collected TAP Device samples provide similar HbA1c test results when compared to venous blood samples collected by a healthcare worker. The study also demonstrated sufficient repeatability for HbA1c testing when multiple samples are self-collected with the TAP Device.

5.3. Standards/Guidance Documents Referenced

The following Standards/Guidance Documents relevant to the proposed change in indications are listed below.

- *Guidance for Industry and FDA Staff* – Deciding When to Submit a 510(k) for a Change to an Existing Device, dated October 25, 2017
- Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline, CLSI Document EP09-A3. (2013).
- Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline, CLSI document GP-34-A. CLSI (2010).
- User Verification of Precision and Estimation of Bias; Approved Guideline, CLSI document EP15-A3. CLSI (2014).