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

## I Background Information:

### A 510(k) Number

K250609

### B Applicant

Sober IP LLC

### C Proprietary and Established Names

Sober Self-Test

### D Regulatory Information

| Product Code(s) | Classification | Regulation Section | Panel |
|---|---|---|---|
| DIC | Class II | 21 CFR 862.3040 - Alcohol Test System | TX - Clinical Toxicology |

## II Submission/Device Overview:

### A Purpose for Submission:

New Device

### B Measurand:

Saliva Alcohol

### C Type of Test:

Qualitative, chromogenic, visually read color change

## III Intended Use/Indications for Use:

**A Intended Use(s):**
See Indications for Use below.

**B Indication(s) for Use:**
Sober Self-Test is a qualitative screening test used to detect the presence of ethyl alcohol in human saliva. The test detects Alcohol Concentrations greater than or equal to 0.02%. Results are used in the diagnosis of alcohol use or intoxication. For In Vitro diagnostic use. The assay is a disposable test for one-time use.

**C Special Conditions for Use Statement(s):**
OTC - Over The Counter

**D Special Instrument Requirements:**

N/A

## IV Device/System Characteristics:

**A Device Description:**

The Sober Self-test is a visually read qualitative test for the detection of alcohol using saliva. The device is composed of a test pad on a strip employed for testing alcohol by visually reading the color change of the pad. The test strip detects the relative Blood Alcohol Concentration (BAC) at 0.02%. The device consists of a box of 2, 3, 6, 12, or 24 individually packaged single test strips each designed for single use and to be disposable, and instruction for use.

**B Principle of Operation:**

Sober Saliva Sobriety self-test strips are designed to detect the blood alcohol concentration (BAC) in saliva. The reagent pads on the strips contain enzymes (alcohol oxidase and horseradish peroxidase) and a chromogen (tetramethylbenzidine). When the strip pads are in contact with saliva containing ethanol for more than 3 minutes, the following chemical reactions are observed:

- The first reaction, which is catalyzed by alcohol oxidase consists of an oxidation of ethanol that produces acetaldehyde and hydrogen peroxide.
- The second reaction which uses horseradish peroxidase as a catalyst oxidases tetramethylbenzidine (TMB) to its one-electron oxidation product in the presence of the hydrogen peroxide formed in the first step. This reaction produces a blue color.

When the concentration of BAC is equal or greater than 0.02%, the strip pad will turn blue.

## V Substantial Equivalence Information:

**A Predicate Device Name(s):** Alco-screen 02

**B Predicate 510(k) Number(s):** K121256

**C Comparison with Predicate(s):**

| **Device & Predicate Device(s):** | K250609 | K121256 |
|---|---|---|
| Device Trade Name | Sober Saliva Sobriety Self-test strips | Alco-screen 02 |
| **General Device Characteristic Similarities** | | |
| Intended Use/Indications For Use | For the qualitative detection of ethyl alcohol in Saliva. | Same |
| Technological Characteristics | Chromogenic reaction | Same |
| Enzyme Used | Alcohol Oxidase | Same |
| Interpretation Visual | Visual color change | Same |
| **General Device Characteristic Differences** | | |
| Reading Time | 3 minutes | 4 minutes |

## VI Standards/Guidance Documents Referenced:

None

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

1. Precision/Reproducibility:

The imprecision of the device was evaluated by reading known spiked alcohol concentrations (0%, 0.008%, 0.01%, 0.02%, 0.08%, and 0.2%) on three lots of strips, with 10 replicates from each lot and read by 3 operators. The strips were read by trained technicians who were presented blindly from each of the 6 saliva alcohol standards and were randomly presented for testing. The results are presented in the table below:

| | | | Operator 1 | | Operator 2 | | Operator 3 | |
|---|---|---|---|---|---|---|---|---|
| Concentration (% BAC) | Lot # | N | Negative | Positive | Negative | Positive | Negative | Positive |
| 0 | 1 | 30 | 10 | 0 | 10 | 0 | 10 | 0 |
| | 2 | 30 | 10 | 0 | 10 | 0 | 10 | 0 |
| | 3 | 30 | 10 | 0 | 10 | 0 | 10 | 0 |
| 0.008 | 1 | 30 | 10 | 0 | 10 | 0 | 10 | 0 |
| | 2 | 30 | 10 | 0 | 10 | 0 | 10 | 0 |
| | 3 | 30 | 10 | 0 | 10 | 0 | 10 | 0 |
| 0.01 | 1 | 30 | 9 | 1 | 9 | 1 | 9 | 1 |
| | 2 | 30 | 10 | 0 | 9 | 1 | 10 | 0 |
| | 3 | 30 | 10 | 0 | 9 | 1 | 9 | 1 |
| 0.02 | 1 | 30 | 0 | 10 | 0 | 10 | 0 | 10 |
| | 2 | 30 | 0 | 10 | 0 | 10 | 0 | 10 |
| | 3 | 30 | 0 | 10 | 0 | 10 | 0 | 10 |
| 0.03 | 1 | 30 | 0 | 10 | 0 | 10 | 0 | 10 |
| | 2 | 30 | 0 | 10 | 0 | 10 | 0 | 10 |
| | 3 | 30 | 0 | 10 | 0 | 10 | 0 | 10 |
| 0.08 | 1 | 30 | 0 | 10 | 0 | 10 | 0 | 10 |
| | 2 | 30 | 0 | 10 | 0 | 10 | 0 | 10 |
| | 3 | 30 | 0 | 10 | 0 | 10 | 0 | 10 |
| 0.20 | 1 | 30 | 0 | 10 | 0 | 10 | 0 | 10 |
| | 2 | 30 | 0 | 10 | 0 | 10 | 0 | 10 |
| | 3 | 30 | 0 | 10 | 0 | 10 | 0 | 10 |

2. Linearity:

   Not Applicable. This assay is intended for qualitative screening determination.

3. Analytical Specificity/Interference:

   The sponsor performed studies to evaluate the effect of substances which may be present in the saliva sample as well as a range of lighting and temperature conditions.

   Substances that are consumed or used orally:
   The sponsor evaluated the effect of cigarette smoke, chewing tobacco, mouthwash with alcohol, chewing gum, cough syrup and breath spray on the assay. For each potential interferent, samples run with 3 test strips in replicate. Half of the samples were spiked with 0.02% ethanol immediately after exposure to oral substance, the other half remained alcohol-free. Saliva was applied to test strip at 1 minute and 15 minutes after consumption or use of the potential interferents. Samples were read after 3 minutes by trained technicians. There were no false positives or false negatives when samples were read at 15 minutes after use or consumption of the potential interferents. False positives were observed for cigarette smoke, chewing tobacco, alcohol containing mouthwash, breath spray and cough syrup when read at one minute. However, the labeling specifies that users should not consume anything or have anything in the mouth for at least fifteen minutes prior to use.

Volatile Substances:
The sponsor conducted a study to assess the potential for positive or negative interference from volatile substances. The volatile substance was spiked into alcohol-free saliva samples and samples with alcohol concentrations of 0.008, 0.02, and 0.032% BAC. No interference was seen for acetone, 2-butanol, glycerol, or isopropanol at the concentrations listed below.

| Volatile Substance | Concentration at which no interference was observed |
|---|---|
| Acetone | 1.0% |
| 1-Butanol | 0.0005% |
| 2-Butanol | 1.0% |
| Glycerol | 1.0% |
| Isopropanol | 0.5% |
| Methanol | 0.0002% |

Temperature:
The effect of temperature on the proposed device test was evaluated using alcohol-free saliva from 10 volunteers spiked at 3 concentrations (0.008%, 0.02%, 0.032%) tested at 2 different temperature conditions: 10°C and 40°C. All samples and test strips were placed at different temperatures and allowed to equilibrate for 15 min prior to testing. The test pad of each strip was saturated with each sample and allowed to stand for 3 minutes prior to reading the result. A total of 3 replicates were tested for each sample at each temperature and all tests gave expected results. The labeling instructs the user to bring all test items to room temperature before use.

Lighting:
The effect of lighting on the device was evaluated by reading known spiked alcohol concentrations of 0, 0.008, 0.020 and 0.032% in daylight, under fluorescent, incandescent, sodium vapor and mercury vapor lighting. The study used three lots of strips. Three replicates were tested for each of the standards under each of five different lighting conditions using the standard test procedure. The strips were read by trained technicians. There were no deviations from the expected results using daylight, under fluorescent, incandescent and mercury vapor lighting. Under the sodium vapor lighting for the negative and 0.008% sample, the undeveloped reactive chemical square was more evident as noted by the trained technician. In the hands of an untrained user, this may be erroneously identified as a positive signal. The labeling instructs the user not to read the test results under sodium vapor light.

4. Assay Reportable Range:

   Not Applicable. This assay is intended for qualitative screening determination.

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

   The sponsor provided a description of traceability protocols that was determined to be adequate.

6. Detection Limit:

Analytical performance of the device is described in precision section VII.A.1 above.

7. Assay Cut-Off:

Analytical performance of the device around the claimed cutoff is described in precision section VII.A.1 above.

**B Comparison Studies:**

1. Method Comparison with Predicate Device:

The Sober Self-Test test results were compared to results from the BACtrack S80 Breathalyzer. After reading the package insert eighty-four participants (56 drinkers and 28 non-alcohol drinkers), performed the Sober Self-Test at 7 intended use sites. Upon completion of the self-test, each participant was tested using the BACtrack S80 Breathalyzer. Results were interpreted by the lay user followed by the trained test administrators. All participants used and interpreted the test correctly and all test results were in agreement with the Breathalyzer.

| | BACtrack S80 Breathalyzer Concentration (%) | |
|---|---|---|
| Sober Self-Test | 0.0 | ≥0.020 |
| Negative | 28 | 0 |
| Positive | 0 | 56 |

Additional clinical study information was provided which compared Sober Self-Test results to a commercially available test when measuring 138 positive and 62 negative specimens. All Sober Self-Test device results were concordant with the commercial method.

2. Matrix Comparison:

Not applicable. The device can only be used to test saliva samples.

**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):

Reading Time Study:
The effect of various reading times on the Sober Self-Test were evaluated using non-alcohol-consuming volunteer saliva samples spiked with control solutions to obtain alcohol concentrations at (0.00, 0.008, 0.02 and 0.20% BAC). The test pad for each strip was

saturated with a sample and read at 2-, 3-, 5-, 6- and 15-minute minutes. A total of 3 replicates were tested for each read time for each sample.

The results support the suggested read time of 3 minutes. The labeling states that the test results must be interpreted 3 minutes after sample application, and no longer than 5 minutes after sample application.

**D Clinical Cut-Off:**

Not applicable.

**E Expected Values/Reference Range:**

Using these types of devices, alcohol is not detectable in the saliva of persons who have not ingested alcohol.

## 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.