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

A. 510(k) Number:

k121256

B. Purpose for Submission:

New Device

C. Measurand:

Saliva Alcohol

D. Type of Test:

Qualitative, chromogenic, visually read color change

E. Applicant:

Chematics Inc.

F. Proprietary and Established Names:

Alco-Screen 02 Saliva Alcohol Test

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DIC	II	Alcohol Test System 21 CFR 862.3040	Toxicology

H. Intended Use:

1. Intended use(s):

   Please see indications for use below.

2. Indication(s) for use:

   The ALCO-SCREEN® 02 is a qualitative screening test used to detect the presence of ethyl alcohol in human saliva. The test detects relative Blood Alcohol Concentrations

(BAC) greater than or equal to 0.02%. Results are used for the diagnosis of alcohol intoxication. For in vitro diagnostic use. The assay is a disposable test for one-time use.

3. Special conditions for use statement(s):

   Over the counter use

4. Special instrument requirements:

   None – each device is single use and self-contained

I. Device Description:

ALCO-SCREEN® 02 is a visually read qualitative test for the detection of alcohol using saliva. It consists of a visually interpreted test strip that develops a distinctly colored line across the test pad when wetted with human saliva with a BAC of greater than or equal to 0.02%. The test strip indicates the relative Blood Alcohol Concentration (BAC) at 0.02% or greater. The device consists of a box of 24 individually packaged single test strips each designed for single use and to be disposable, and instruction for use.

The active reagents in the enzymatic solution include: alcohol oxidase enzyme from yeast, peroxidase enzyme from horseradish and tetramethylbenzidine.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   QED A150 Saliva Alcohol Test

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

   k894001

3. Comparison with predicate:

Item	Alco-Screen® 02 (Candidate Device)	QED A150 Saliva Alcohol Test (Predicate Device - (K894001)
Indications for use	ALCO-SCREEN® 02 is a qualitative screening test used to detect alcohol using human saliva. The test detects Blood Alcohol Concentration (BAC) greater than or equal to 0.02%. For in vitro diagnostic use.	Same

Technological Characteristics	Chromogenic reaction	Chromogenic reaction
Enzyme Used	alcohol oxidase	alcohol dehydrogenase
Measuring Units	BAC%	BAC% (and mg/dL)
Interpretation	Visual color change	Same
Reading Time	4 minutes	2 minutes
Calibration	None required	Same
Shelf Life	12 months at 10-27°C (50-80°F)	12 months at 15-30°C (59-86°F)

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

None were referenced.

L. Test Principle:

The Alco-Screen® 02 test consists of a plastic strip containing alcohol oxidase on the tip. On contact with saliva a pair of coupled enzymatic reactions that catalyze the oxidation of tetramethylbenzidine in the presence of short-chain, linear aliphatic alcohols such as methanol or ethanol will take place. Samples containing a BAC greater than or equal to 0.02% will develop a distinctly colored line across the reagent pad after an incubation time of 4 minutes. The absence of a distinctly colored line after incubating with saliva for 4 minutes indicates a negative result i.e. a BAC less than 0.02%.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

1. Intra-assay precision around the cutoff

The imprecision of the device was evaluated by reading known spiked alcohol concentrations (0%, 0.008%, 0.02% and 0.032%) on three lots of strips, with 20 replicates from each lot and read over 3 days. The alcohol concentrations were confirmed with a commercially available enzymatic NAD-ADH reagent kit. The strips were read by trained technicians. Samples were presented blindly from each of the four saliva alcohol standards and were randomly presented for testing. The results are presented in the tables below:

			DAY 1		DAY 2		DAY 3	
Concentration (% BAC)	Lot #	N	Negative	Positive	Negative	Positive	Negative	Positive
0	1	60	20	0	20	0	20	0
	2	60	20	0	20	0	20	0
	3	60	20	0	20	0	20	0
0.008	1	60	20	0	20	0	20	0
	2	60	18	2	19	1	19	1
	3	60	19	1	18	2	20	0
0.02	1	60	2	18	0	20	1	19
	2	60	0	20	0	20	0	20
	3	60	0	20	0	20	0	20
0.032	1	60	0	20	0	20	0	20
	2	60	0	20	0	20	0	20
	3	60	0	20	0	20	0	20

b. Linearity/assay reportable range:

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

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

Each lot of test strips is verified during manufacturing by using control solutions that have been prepared from purchased ethanol solutions that are confirmed using a previously cleared enzymatic NAD-ADH Reagent kit. The control results from the test strips are read visually by comparing to the color chart and then the color intensity verified using a spectrophotometer.

d. Detection limit:

To assess the possibility of false positives, the sponsor performed a study analyzing alcohol-free (0% BAC) saliva samples. Three lots were analyzed 20 times for a total n of 60. There were 0 false positives observed when measuring zero concentration samples.

e. Analytical specificity:

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, chewing gum, cough syrup and breath spray on the assay. For each potential interferent, samples were collected from ten volunteers, of which five were drinkers and five were non-drinkers. Results were read at 1 minute and 15 minutes after consumption or use of the potential interferents. Samples were read 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 and alcohol containing mouthwash, breath spray and cough syrup when read at one minute. 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%

The concentration at which no interference is observed in Alco-Screen® 02 test results was determined for each substance. Those substances and their concentrations are documented in the Package Insert.

Temperature:

The effect of temperature on the Alco-Screen® 02 test was evaluated using alcohol-free saliva from volunteers and control solutions prepared at the cutoff level and at +/- 60% of each cut off level tested at 2 different temperature conditions: 10 and 40°C. The concentration of the alcohol in the prepared solution was confirmed using an enzymatic NAD-ADH reagent supplied by Pointe Scientific. All samples and test strips were placed at different temperatures and allowed to equilibrate for 10 min prior to testing. The test pad of each strip was saturated with each sample and allowed to stand for 2 minutes prior to reading the result. A total of 20 replicates were tested for each sample at each temperature. Results are summarized in the table below.

Temperature Testing at 10ºC

Standard Concentration	Negative	Positive	% Correct
0.008%	10	0	100%
0.020%	2	8	80%
0.032%	0	10	100%

Temperature Testing at 40ºC

Standard Concentration	Negative	Positive	% Correct
0.008%	10	0	100%
0.020%	3	7	70%
0.032%	0	10	100%

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. Twenty 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 stripe 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 for the Alco-Screen® will therefore instruct the user not to read the test results under sodium vapor light.

f. Assay cut-off:

Analytical performance of the device around the claimed cutoff is described in precision section (1a.) above.

2. Comparison studies:

a. Method comparison with predicate device:
The Alco-Screen® 02 test results were compared to results from the Alco-Sensor IV (Evidential Breath Testing Device). After reading the package insert thirty five participants, designated as the testing volunteers performed the Alco-Screen® 02 test on fifty two participants (27 drinkers and 25 non-alcohol drinkers). Results were interpreted by the lay user followed by the trained facilitators. The trained facilitators also performed the breath alcohol test using the Alco-Sensor IV. A total of 279 test

strips were used for the study.

	Alco-Sensor IV Concentration (%)		
Alco-Screen® 02	0.0	0.008 to < 0.020	≥ 0.020
Negative	95	2	1
Positive	0	15	166

b. Matrix comparison:

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

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):

Reading Time Study:

The effect of various reading times on the Alco-Screen 02 Saliva Alcohol Test were evaluated using negative saliva samples and saliva spiked with control solutions to obtain alcohol concentrations at the cut off and at +/-60% of the cut off. The test pad for each strip was saturated with sample and read at 4, and 5 minutes. A total of 20 replicates were tested for each read time for each sample.

The results support the suggested read time of 4 to 5 minutes. The labeling states that the test results must be interpreted 4 minutes after sample application, and no longer than 5 minutes after sample application.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

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

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.