

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

A. 510(k) Number:

k100879

B. Purpose for Submission:

New Device

C. Measurand:

Breath Alcohol

D. Type of Test:

Semi-quantitative visually read color change

E. Applicant:

Contralco

F. Proprietary and Established Names:

Contralco Single Use Breath-Alcohol Tester (0.02, 0.04, 0.05, 0.06, 0.08, and 0.10% BAC)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DJZ	Class I, reserved	862.3050	91, Toxicology

H. Intended Use:

1. Intended use(s):

See indication for use below.

1. Indication(s) for use:

The Contralco Alcohol Breath Tester is an in vitro medical device to semi-quantitatively detect the presence of alcohol in the human breath. It is a disposable

screening device for one-time use. The detector is available at several detection cut-offs: 0.02, 0.04, 0.05, 0.06, 0.08, and 0.10 relative percent Blood Alcohol Concentration (BAC). The device is used only as a screening device and is only an indication of the possible presence of alcohol in the blood of the test subject.

3. Special conditions for use statement(s):

For Over the Counter use

4. Special instrument requirements:

Not applicable.

I. Device Description:

The Contralco Alcohol Breath Tester device is made up of 2 parts: the reagent tube and the plastic bag. Yellow crystals in the reagent tube are coated with Chromium VI oxide and sulfuric acid. The amount of these indicator chemicals is adjusted according to the selected cut-off of the tester. The user exhales into the reagent tube and fills the plastic bag with exhaled air. A color change is produced when alcohol vapors (squeezed from collected exhaled air in the plastic bag portion of the tester) are oxidized to acetic acid and the indicator chemicals change to chromium sulfate. The majority of crystals change from yellow to light green when alcohol vapors are present at a level equal to or exceeding the labeled cut-off of the tester.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Redline disposable Alcohol Breath Tester

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

k072953

2. Comparison with predicate:

	Candidate Device	Predicate (k072953)
Indication for use	Detect the presence of alcohol in the human breath	Same
Target Populations	Over the Counter	Same
Anatomical Site	Mouth	Same
Test sample	Human Breath	Same

Composition of Reagent	Yellow Crystals	Same
Collection Device	Plastic bag	Same
Blowing Time	12 seconds	Same
Result Interpretation	Extent of color change	Same
Measurement Range	Separate devices are pre-calibrated to turn color at different cut-offs: 0.02%, 0.04%, 0.05%, 0.06%, 0.08%, 0.10%	Separate devices are pre-calibrated to turn color at different cut-offs: 0.02%, 0.04%, 0.05%, 0.08%, 0.10%
Protection of alcohol breath test against humidity	The reactant is placed in a glass tube with opercula at both extremities	Amorphous silica gel particles act as protective barrier at either end of tube

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

None referenced.

L. Test Principle:

The Contralco alcohol breath tester contains chemicals that change color in the presence of alcohol in human breath. First, the user pushes in both ends of the glass tube, sliding them until the dotted lines. Secondly, the user blows into the blue valve, filling the plastic bag with one breath only and completely inserts the blue perforation of the glass tube into the blue valve. Thirdly, the user pushes the plastic bag slowly, in about 12 seconds, until it is completely emptied. On contact with alcohol, the reactant will turn green. Each device has a black line which indicates the cut-off concentration for each device. If the green color reaches or exceeds the black line, the user has exceeded the allowed limit of alcohol per liter of air.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The sponsor evaluated the precision and accuracy for each of the six Contralco Alcohol Breath Testers (0.02, 0.04, 0.05, 0.06, 0.08, and 0.1% BAC) using a Breath Alcohol Sample Simulator, which provides an alcohol-in-air test sample with known alcohol concentrations, flow rate, and air composition. On contact with alcohol, the reactant will turn green. Each device has a black line which indicates the cut-off concentration for each device. If the green color reaches or exceeds the black line, the user has exceeded the cut-off concentration and the result is considered positive. If the

green color fails to reach the black line, the result is considered negative.

Testing was performed by 10 individuals under 5 different lighting sources using 20 Contralco Breath Alcohol Testers at each cutoff concentration. The concentrations used were 0% BAC, 60% below the cut-off concentration, and 60% above the cut-off concentration.

The table below shows the number of devices that resulted in the expected outcome (negative or positive) of the number of devices evaluated.

	Concentration	0.02	0.04	0.05	0.06	0.08	0.1
Fluorescent	0%	200/200	200/200	200/200	200/200	200/200	200/200
	-60% of cut-off	200/200	200/200	200/200	200/200	200/200	200/200
	+60% of cut-off	200/200	200/200	200/200	200/200	200/200	200/200
Daylight	0%	200/200	200/200	200/200	200/200	200/200	200/200
	-60% of cut-off	200/200	200/200	200/200	200/200	200/200	200/200
	+60% of cut-off	200/200	200/200	200/200	200/200	200/200	200/200
Incandescent	0%	200/200	200/200	200/200	200/200	200/200	200/200
	-60% of cut-off	200/200	200/200	200/200	200/200	200/200	200/200
	+60% of cut-off	200/200	200/200	200/200	200/200	200/200	200/200
Sodium Vapor	0%	200/200	200/200	200/200	200/200	200/200	200/200
	-60% of cut-off	200/200	200/200	198/200	200/200	200/200	200/200
	+60% of cut-off	200/200	200/200	200/200	200/200	200/200	200/200
Mercury Vapor	0%	200/200	200/200	200/200	200/200	200/200	200/200
	-60% of cut-off	200/200	200/200	200/200	198/200	197/200	200/200
	+60% of cut-off	200/200	200/200	200/200	200/200	200/200	200/200
% Agreement		100%	100%	100%	99.86%	99.90%	100%

b. Linearity/assay reportable range:

Not applicable. The assay is a semi-quantitative assay.

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

The concentrations are prepared from commercially available solutions and are verified on certified evidential breath alcohol testers. These solutions are used to verify the cut-off concentration of the devices during manufacture.

The sponsor performed a stability assessment of all devices (0.02, 0.04, 0.05, 0.06, 0.08, and 0.1 % BAC) to evaluate the stability of the breath alcohol test results over time. This study served to validate the reported read time window claim of 2 to 15 minutes provided on the device labeling. Using simulated breath, (50) samples that were 60% below the device cut-off and (50) samples that were 60% above the cut-off were randomized and blinded prior to interpretation by (5) individuals at the end of 2, 5, 8, 11, and 15 minutes. Identical results were obtained for all devices at each time point tested. The results are presented in the table below:

Contralco Alcohol Breath Tester Results (Cut-off: 0.02, 0.04, 0.05, 0.06, 0.08, 0.1)		
Time	-60% of cut-off	+60% of cut-off
2 min	50/50 Negative	50/50 Positive
5 min	50/50 Negative	50/50 Positive
8 min	50/50 Negative	50/50 Positive
11 min	50/50 Negative	50/50 Positive
15 min	50/50 Negative	50/50 Positive

d. Detection limit:

The NHTSA guidelines do not specifically address the detection limit of breath alcohol devices but require testing at a % BAC of zero (blank reading) to assess the possibility of false positives. The sponsor included a zero concentration sample in their precision study above. Non-alcoholic breath was used as the sample. There were no false positives observed when measuring zero concentration samples.

e. Analytical specificity:

The sponsor performed the following studies for each cut-off concentration (0.02, 0.04, 0.05, 0.06, 0.08, 0.10 %BAC) to evaluate the potential interference on the test results from cigarette smoke, temperature, and vibration.

Cigarette Smoke – (5) alcohol-free volunteers were asked to conduct (4) breath alcohol tests for each device cut-off concentration while smoking a cigarette. The testing was spread out to cover the duration of time it took to completely smoke a cigarette. The Contralco Alcohol Breath Testers produced no false positive or false negative results under these conditions.

Temperature – The sponsor assessed the effect of temperature at 10 and 40°C. A total of (40) different devices were stored and tested at each temperature for each cut-off concentration. Using simulated breath, (20) samples that were 60% below the device cut-off and (20) samples that were 60% above the cut-off were tested. The results are presented in the table below:

Contralco Alcohol Breath Tester Results				
	10°C		40°C	
Cut-off	-60% of cut-off	+60% of cut-off	-60% of cut-off	+60% of cut-off
0.02	20/20 Negative	20/20 Positive	20/20 Negative	20/20 Positive
0.04	20/20 Negative	20/20 Positive	20/20 Negative	20/20 Positive
0.05	20/20 Negative	20/20 Positive	20/20 Negative	20/20 Positive
0.06	20/20 Negative	20/20 Positive	20/20 Negative	20/20 Positive
0.08	20/20 Negative	20/20 Positive	20/20 Negative	20/20 Positive
0.1	20/20 Negative	20/20 Positive	20/20 Negative	20/20 Positive

Vibration- A total of (40) different devices for each cut-off concentration were placed in a box and mounted on a magnetic agitator for 5 minutes. Using simulated breath, (20) samples that were 60% below the device cut-off and (20) samples that were 60% above the cut-off were tested. The results are presented in the table below:

Contralco Alcohol Breath Tester Results		
	-60% of cut-off	+60% of cut-off
Cut-off		
0.02	20/20 Negative	20/20 Positive
0.04	20/20 Negative	20/20 Positive
0.05	20/20 Negative	20/20 Positive
0.06	20/20 Negative	20/20 Positive
0.08	20/20 Negative	20/20 Positive
0.1	20/20 Negative	20/20 Positive

As an added precaution, the device is wrapped inside a bag to protect the tester from light. The manufacturer’s labeling instructs the user to wait 20 minutes after drinking before taking a reading, to avoid smoking during the test, and to store the device in a dark place between 10°C and 40°C.

f. Assay cut-off:

Each device will produce a blue-green color at or above the following cut-off concentration: 0.02, 0.04, 0.05, 0.06, 0.08, 0.10 % BAC.

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor performed a consumer study to determine if consumers could correctly use and interpret the device using only the supplied User’s Manual, and to compare the results to a professional quantitative device (the LION device). The study was conducted at the exit of a nightclub. Each participant took their breath alcohol reading with the 0.05% Contralco tester and recorded their result. Immediately afterward, the participants were administered a breath alcohol test using the LION operated by a trained individual. A total of

59 measures were taken. The reported age range of the participants was from 21 to 50 years of age. There were 38 males and 21 females who participated in the trial. Accuracy results are presented in the table below:

Contralco 0.05% Tester Result	Quantitative Results			
	Less than 60% the cut-off (<0.02%)	Near Cut-off Negative (0.02 to 0.05%)	Near Cut-off Positive (>0.05 to 0.08%)	More than + 60% of cut-off (> 0.08%)
Positive	0	0	10	17
Negative	18	13	1	0

After the study, participants were asked questions about ease of use and interpretation. The results are presented below:

Question	Strongly Disagree	Disagree	Don't Know	Agree	Strongly Agree
The Contralco instructions are easy to understand and follow	0	0	0	16	43
It is easy to see and read the Contralco results	0	0	0	25	34

b. Matrix comparison:

Not applicable. This device may be used with breath samples 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):

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

For this type of device, alcohol should not be detectable in the breath 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.