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

A. 510(k) Number:

k102225

B. Purpose for Submission:

New Devices

C. Measurand:

Breath Alcohol

D. Type of Test:

Semi-quantitative and qualitative visually read color change

E. Applicant:

AlcoPro, Inc

F. Proprietary and Established Names:

Alco-Breath Tube and CheckPoint® Breath Alcohol Test

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DJZ	Class I, reserved	21 CFR 862.3050	Toxicology (91)

H. Intended Use:

1. Intended use(s):

   Refer to indication for use below.

2. Indication(s) for use:
   Alco-Breath Tube breath alcohol test

   The Alco-Breath Tube is a device to test for alcohol in human breath. It is a disposable

device designed for one-time use and is a screening test that gives preliminary results. This device provides a semi-quantitative estimate of alcohol levels in breath. The ABT-08 device gives readings between 0 and 0.08% BAC and the ABT-15 device gives readings between 0 and 0.15% BAC.

CheckPoint breath alcohol test

The CheckPoint breath alcohol test is a device to test for alcohol in human breath. It is a disposable device designed for one-time use and is a screening test that gives preliminary results. The test is available at cut-offs of 0.02, 0.04, 0.05, and 0.08% BAC.

3. Special conditions for use statement(s):

Over-the-counter use

The sponsor includes the following in the Warnings, Precautions, and Limitations section of the labeling:

"Do not use this test to determine if it is safe for you to drive. The actual result may be significantly higher or lower than indicated by this product. The Alco-Breath Tube is not intended to legally determine the presence of alcohol or concentration of alcohol in a person. This product should be used only as a screening device and is only an indication of the possible presence of alcohol in the blood of the user. The exact level of alcohol in the blood cannot be accurately determined by using this product."

4. Special instrument requirements:

Not applicable.

I. Device Description:

Alco-Breath Tube breath alcohol test

The Alco- Breath Tube is a visually read semi-quantitative test for the detection of alcohol in exhaled breath. It indicates relative Blood Alcohol Concentration (BAC) between 0 and 0.08 (ABT -08) or 0.15 (ABT-15). The device consists of two parts, a glass tube containing treated silica gel and a balloon assembly.

CheckPoint breath alcohol test

The Breath Alcohol Test is a visually read semi-quantitative test for the detection of alcohol in exhaled breath. It indicates relative Blood Alcohol Concentration (BAC) at four different cut-off levels (0.02, 0.04, 0.05, and 0.08% BAC). The device is designed as

a glass ampule containing reagent treated silica gel and held inside a flexible plastic tube with porous filters. An optional volumetric bag is used to collect human breath for testing.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   BreathScan Alcohol Detector

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

   k060761

3. Comparison with predicate:

Feature	Predicate Device: BreathScan® Alcohol Detector (K060761)	New Device: Alco-Breath Tube	New Device: CheckPoint® Breath Alcohol Test
Intended Use	Detect presence of alcohol in exhaled breath	Same as predicate	Same as predicate
Target Population	Over the counter	Same as predicate	Same as predicate
Calibration/ Accuracy Checks	None required	Same as predicate	Same as predicate
Methodology	Chromogenic reaction	Same as predicate	Same as predicate
Anatomical Site	Mouth	Same as predicate	Same as predicate
Test Sample	Exhaled human breath	Same as predicate	Same as predicate
Blowing Time	12 seconds	1 minute	Same as predicate
Test Time	2 minutes	Same as predicate	Same as predicate
Result	Qualitative	Same as predicate; also provides semi-quantitative results	Same as predicate
Interpretive Method	Visual Color Change	Same as predicate	Same as predicate
Measuring Units	BAC %	Same as predicate	Same as predicate
Measurement Range	Separate devices available at different cut-off levels: 0.02%, 0.04%, 0.05%, and 0.08%	Separate devices available at different cut-off levels: 0.04% and 0.08%	Same as predicate
Mouthpiece	None Required	Same as predicate	Same as predicate
Collection Device	None Required	Balloon	Optional volumetric bag

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

The sponsor states conformance to the following standards:

- Department of Transportation National Highway Traffic Safety Administration [NHTSA 73 FR 16956] Highway Safety Programs; Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids

L. Test Principle:

The Breath Alcohol Detector consists of crystals that employ a solid-phase chemistry system based on a chromogenic chemical reaction. Alcohol, if present in the exhaled breath, reacts with the coated crystals to produce a color change. This color change is proportional to the concentration of alcohol in the breath, which is an approximation of relative Blood Alcohol Concentration (BAC). The light yellow crystals produce a color change when alcohol vapors are oxidized to acid and the indicator chemical changes to chromic ion. Results are interpreted as positive when the majority of the crystals change from yellow to green. This indicates that alcohol vapors are present at a concentration approximately equal to the value indicated on the tube for Alco breath tube or greater than or equal to the cutoff for the Breath alcohol test.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Alco-Breath Tube:

The ABT-08 can measure between 0.00 - 0.08% BAC and the ABT-15 measures BAC between 0.00 - 0.15%. The ABT – 08 tester was evaluated at 0.00, 0.016, and 0.064% BAC. For this study, any result less than 0.04% BAC was interpreted as negative and any result greater than 0.04% BAC was interpreted as positive.

The ABT – 15 was evaluated at 0, 0.032, and 0.128% BAC. For this study, any result less than 0.08% BAC was interpreted as negative and any result greater than 0.08% BAC was interpreted as positive.

Blood Alcohol Concentrations were simulated by a Breath Alcohol Sample Simulator (BASS), which provides an alcohol-in-air test sample with known alcohol concentrations, flow rate, and air composition. Five different lighting conditions were tested: Fluorescent, daylight, incandescent, sodium vapor, and mercury vapor.

Testing was performed by 3 operators, 3 days, and up to 3 lots for a total of 600 results.. For the ABT–08 device, testing consisted of: 200 trials at a Blood Alcohol Concentration

(BAC) of 0.064, 200 trials at a BAC of 0.016, and 20 trials at a BAC of 0.000. For the ABT–15 device, testing consisted of 20 trials at a BAC of 0.128, 20 trials at a BAC of 0.032, and 20 trials at a BAC of 0.000.
Results were as follows:

Lighting	Concentration	ABT-08 (expected result/observed result)
Daylight	**0%**	200/200
	0.016%	200/200
	0.064%	200/200
Incandescent	**0%**	200/200
	0.016%	200/200
	0.064%	200/200
Fluorescent	**0%**	200/200
	0.016%	200/200
	0.064%	200/200
Mercury Vapor	**0%**	200/200
	0.016%	200/200
	0.064%	200/200
Sodium Vapor	**0%**	200/200
	0.016%	200/200
	0.064%	200/200

Lighting	Concentration	ABT-15 (expected result/observed result)
Daylight	**0%**	200/200
	0.032%	200/200
	0.128%	200/200
Incandescent	**0%**	200/200
	0.032%	200/200
	0.128%	200/200
Fluorescent	**0%**	200/200
	0.032%	200/200
	0.128%	200/200
Mercury Vapor	**0%**	200/200
	0.032%	200/200
	0.128%	200/200

Sodium Vapor	**0%**	200/200
	0.032%	200/200
	0.128%	200/200

CheckPoint® Breath Alcohol Test:
For each of the CheckPoint® Breath Alcohol Test device type (with cut-off levels of 0.02, 0.04, 0.05, and 0.08) testing was performed by 3 operators, over 3 days, and up to 3 lots for a total of 600 results. Blood Alcohol Concentrations are simulated by a Breath Alcohol Sample Simulator (BASS), which provides an alcohol-in-air test sample with known alcohol concentrations, flow rate, and air composition. The simulator is used to produce a simulated breath sample at - 60% cut-off and + 60% cut-off. Five different lighting conditions were tested: Fluorescent, daylight, incandescent, sodium vapor, and mercury vapor.

For devices with 0.02 cut-off level, tests consist of: 200 trials at a Blood Alcohol Concentration (BAC) of 0.032, 20 trials at a BAC of 0.008, and 200 trials at a BAC of 0.000. For devices with 0.04 cut-off level, tests consisted of 200 trials at a BAC of 0.064, 200 trials at a BAC of 0.016, and 200 trials at a BAC of 0.000. For devices with 0.05 cut-off level, tests consist of 200 trials at a BAC of 0.080, 200 trials at a BAC of 0.020, and 200 trials at a BAC of 0.000. For devices with 0.08 cut-off level, tests consisted of 200 trials at a BAC of 0.128, 200 trials at a BAC of 0.032, and 200 trials at a BAC of 0.000. Results were as follows:

Lighting	**Concentration**	**CP-02 w/bag** (expected result/observed result)
Daylight	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Incandescent	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Fluorescent	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Mercury Vapor	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Sodium Vapor	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200

Lighting	Concentration	CP-02 w/o bag (expected result/observed result)
Daylight	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Incandescent	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Fluorescent	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Mercury Vapor	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Sodium Vapor	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200

Lighting	Concentration	CP-04 w/bag (expected result/observed result)
Daylight	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Incandescent	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Fluorescent	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Mercury Vapor	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Sodium Vapor	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200

Lighting	Concentration	CP-04 w/o bag (expected result/observed result)
Daylight	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Incandescent	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Fluorescent	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Mercury Vapor	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Sodium Vapor	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200

Lighting	Concentration	CP-05 w/bag (expected result/observed result)
Daylight	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Incandescent	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Fluorescent	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Mercury Vapor	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Sodium Vapor	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200

Lighting	Concentration	CP-05 w/o bag (expected result/observed result)
Daylight	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Incandescent	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Fluorescent	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Mercury Vapor	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Sodium Vapor	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200

Lighting	Concentration	CP-08 w/bag (expected result/observed result)
Daylight	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Incandescent	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Fluorescent	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Mercury Vapor	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Sodium Vapor	0%	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200

Lighting	Concentration	CP-08 w/o bag (expected result/observed result)
Daylight	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Incandescent	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Fluorescent	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Mercury Vapor	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200
Sodium Vapor	**0%**	200/200
	c/o - 60%	200/200
	c/o + 60%	200/200

b. Linearity/assay reportable range:

Not applicable.

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

Traceability

Alcohol standard solutions at various BAC concentrations were prepared from commercially available solutions and are verified on a certified evidential breath alcohol tester. These solutions were used to verify the cut-off concentration of the devices during manufacture.

Stability

The sponsor provided data to confirm that the CheckPoint breath alcohol test was stable for a period of up to three years from date of manufacture and the Alco-Breath Tube was stable for a period of 18 months from date of manufacture when stored at 50 – 85^{o} F.

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. Precision studies included zero concentration samples in which nonalcoholic human breath was used as the sample. There were no false positives observed when measuring zero concentration samples. See above for precision testing.

e. Analytical specificity:

1. Cigarette smoke

Tests were conducted for each device to evaluate the potential interference on the test results from cigarette smoke. For the Alco-Breath Tube Test, both the ABT – 08 and ABT-15 testers were evaluated. For the CheckPoint® Breath Alcohol Test, tests were conducted for each device cut-off level, 0.02%, 0.04%, 0.05% and 0.08%.
A trained operator conducted the study with volunteers to produce a total of five trials. An alcohol-free volunteer was asked to smoke approximately one half of a cigarette and perform an alcohol test. The volunteer smoked another inhalation and repeated the test to produce a total of five trials. Results of this study show that the devices at each cut-off level produces no positive results from cigarette smoke.

Alco-Breath Tube						
Device	**Lot#**	**Test #1**	**Test #2**	**Test #3**	**Test #4**	**Test #5**
ABT .08	021910	Negative	Negative	Negative	Negative	Negative
ABT .15	021910	Negative	Negative	Negative	Negative	Negative

CheckPoint Breath Alcohol Test							
Device	**Cut Off**	**Lot#**	**Test #1**	**Test #2**	**Test #3**	**Test #4**	**Test #5**
CP .02	0.02%	082808	Negative	Negative	Negative	Negative	Negative
CP .04	0.04%	012209	Negative	Negative	Negative	Negative	Negative
CP .05	0.05%	072309	Negative	Negative	Negative	Negative	Negative
CP .08	0.08%	PREEC6	Negative	Negative	Negative	Negative	Negative

2. Temperature:

Tests were conducted for each device to evaluate the potential interference on the test results from varying temperatures. For the Alco-Breath Tube Test both the ABT – 08 and ABT-15 testers were evaluated. For the CheckPoint® Breath Alcohol Test, tests were conducted for each device cut-off level, 0.02%, 0.04%, 0.05% and 0.08%.
Results were as follows:

Alco-Breath Tube				
Device	**10°**		**40°**	
	0.016% (expected result/observed result)	**0.064% (expected result/observed result)**	**0.016% (expected result/observed result)**	**0.064% (expected result/observed result)**
ABT .08	20/20	20/20	20/20	20/20
Alco-Breath Tube				
Device	**10°**		**40°**	
	0.032% (expected result/observed result)	**0.128% (expected result/observed result)**	**0.032% (expected result/observed result)**	**0.128% (expected result/observed result)**
ABT .15	20/20	**19/20**	20/20	20/20

CheckPoint Breath Alcohol Test with volumetric bag					
Device	**Cut Off Level**	**10°**		**40°**	
		-60%Cut-Off (expected result/observed result)	**+60% Cut-Off (expected result/observed result)**	**-60%Cut-Off (expected result/observed result)**	**+60% Cut-Off (expected result/observed result)**
CP .02	0.02%	20/20	20/20	20/20	20/20
CP .04	0.04%	20/20	20/20	20/20	20/20
CP .05	0.05%	20/20	20/20	20/20	20/20
CP .08	0.08%	20/20	20/20	20/20	20/20

CheckPoint Breath Alcohol Test without volumetric bag					
Device	**Cut Off Level**	**10°**		**40°**	
		-60%Cut-Off (expected result/observed result)	**+60% Cut-Off (expected result/observed result)**	**-60%Cut-Off (expected result/observed result)**	**+60% Cut-Off (expected result/observed result)**
CP .02	0.02%	20/20	20/20	20/20	20/20
CP .04	0.04%	20/20	20/20	20/20	20/20
CP .05	0.05%	20/20	20/20	20/20	20/20
CP .08	0.08%	20/20	20/20	20/20	20/20

3. Vibration:

Tests were conducted for each device to evaluate the potential interference on the test results from vibration. For the Alco-Breath Tube Test, both the ABT – 08 and ABT-15 testers were evaluated. For the CheckPoint® Breath Alcohol Test, tests were conducted for each device cut-off level, 0.02%, 0.04%, 0.05% and 0.08%. Results were as follows:

Device	-60%Cut-Off (expected result/observed result)	+60% Cut-Off (expected result/observed result)
ABT .08	20/20	20/20
ABT .15	20/20	20/20

Device	Cut Off Level	-60%Cut-Off (expected result/observed result)
CP .02	0.02%	20/20
CP .04	0.04%	20/20
CP .05	0.05%	20/20
CP .08	0.08%	20/20

Device	Cut Off Level	-60%Cut-Off (expected result/observed result)
CP .02	0.02%	20/20
CP .04	0.04%	20/20
CP .05	0.05%	20/20
CP .08	0.08%	20/20

f. Assay cut-off:

The CheckPoint® devices produce a blue/green or green/blue color at 0.02%, 0.04%, 0.05%, and 0.08% cut-off levels.

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 devices using only the supplied User's Manual, and to compare the results to a professional quantitative device. For this study, the test was conducted by trained operator(s) and volunteer subject(s). The Alco Breath Tube Test and the CheckPoint® Breath Alcohol Test were compared against an evidentiary alcohol test device.

Thirty (30) drinking subjects were paired with thirty (30) non-drinking subjects. The nondrinking subjects administered breath tests throughout the evening to the drinking

subjects. The tests were performed using the manufacturer's test protocol supplied with the device.

Alco-Breath Tube Comparison study

Sixty-two results as measured by the evidential device fell within the 0 – 0.08% BAC measuring range of the ABT-08 tester. Simple linear regression produces a slope of 0.91, an intercept of 0 and a correlation coefficient of 0.86.

Seven results read greater than 0.08% BAC with the evidential device and read 0.08% BAC (the highest possible reading) on the ABT device.

Four results read greater than 0.08% BAC with the evidential device but less than 0.08% BAC on the ABT device, as follows:

ABT	Evidential
0.04	0.110
0.07	0.131
0.07	0.138
0.04	0.167

The sponsor includes the following in the Warnings, Precautions, and Limitations section of the labeling:

"Do not use this test to determine if it is safe for you to drive. The actual result may be significantly higher or lower than indicated by this product. The Alco-Breath Tube is not intended to legally determine the presence of alcohol or concentration of alcohol in a person. This product should be used only as a screening device and is only an indication of the possible presence of alcohol in the blood of the user. The exact level of alcohol in the blood cannot be accurately determined by using this product."

CheckPoint with Blow Bag Comparison Study

CheckPoint with Blow Bag 0.04% Tester	0.00 to 0.010%	Low Negative >0.010 to 0.020%	Near Cut-off Negative (>0.020 to <0.040%)	Near Cut-off Positive (0.040 to 0.060%)	High Positive (>0.060)
Positive	0	1	9	13	23
Negative	23	6	4	0	0

CheckPoint without Blow Bag Comparison Study

CheckPoint without Blow Bag 0.04% Tester	0.00 to 0.010%	Low Negative >0.010 to 0.020%	Near Cut-off Negative (>0.020 to <0.040%)	Near Cut-off Positive (0.040 to 0.060%)	High Positive (>0.060)
Positive	0	0	10	13	21
Negative	21	7	4	0	0

Instructions for use survey results:

Question:	Yes	No	Strongly Disagree	Agree	Don't Know	Disagree	Strongly Disagree
1. Did you have any problems performing any of the tests?	3	27	N/A	N/A	N/A	N/A	N/A
2. The CheckPoint instructions are easy to understand.	N/A	N/A	19	10	0	1	0
3. The CheckPoint results are easy to interpret.	N/A	N/A	17	12	0	1	0
4. The Alco-Breath Tube instructions are easy to understand.	N/A	N/A	18	10	0	2	0
5. The Alco-Breath Tube results are easy to interpret.	N/A	N/A	16	14	0	0	0

b. Matrix comparison:

Not applicable.

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):

Not applicable

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

   Using these types of devices, alcohol is not 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.