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

A. 510(k) Number:

k093143

B. Purpose for Submission:

New Device

C. Measurand:

Breath Alcohol

D. Type of Test:

Semi-quantitative, visually read color change

E. Applicant:

ACON Laboratories Inc.

F. Proprietary and Established Names:

Mission Breath Alcohol Detector

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.3050, Breath-alcohol test system

2. Classification:

   Class I, reserved

3. Product code:

   DJZ

4. Panel:

   Toxicology, 91

H. Intended Use:

1. Intended use(s):

   Refer to indications for use below.

2. Indication(s) for use:

   The Breath Alcohol Detector is for the semi-quantitative rapid detection of the presence of alcohol in the exhaled breath. The Breath Alcohol Detector indicates relative Blood Alcohol Concentration (BAC) at 0.02%, 0.04%, 0.05%, 0.06%, 0.08% or 0.10% cut-off levels. Measurements obtained by this device are used in the diagnosis of alcohol intoxication

3. Special conditions for use statement(s):

   For Over-the-counter use.

4. Special instrument requirements:

   Not applicable

I. Device Description:

The Breath Alcohol Detector is a visually read semi-quantitative test for the detection of alcohol in exhaled breath. It indicates relative Blood Alcohol Concentration (BAC) at six different cut-off levels. The device consists of a plastic tube, a glass vial encased with reaction crystals (glass ampoule containing reaction granules), two plastic plugs, a blow bag (optional) and a tube label. The tube label indicates the specific cut-off level for each detector. Results are obtained by comparing majority of the color of the crystals with a color block printed on the tube label. The tubes are disposable and intended for one-time use.

The Breath Alcohol Detector is available with or without blow bags. The blow bag is an optional item that may be inserted into one end of the device to provide visual confirmation that the user has blown adequate amount of air into the detector.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Akers Biosciences Inc. BreathScan Alcohol Detectors (0.02, 0.04, 0.05 and 0.08% BAC)

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

   k060761

3. Comparison with predicate:

Similarities		
Item	Predicate Devices	Mission Breath Alcohol Detectors
Cutoffs available	0.02, 0.04, 0.05 and 0.08% BAC	0.02%, 0.04%, 0.05%, 0.06%, 0.08% and 0.10% BAC
Interpretation	Visual Color Change	Same
Calibration	Not applicable	Same
Optimal Lighting Conditions	Incandescent, fluorescent, or indirect sunlight	Same

Differences		
Item	Predicate Devices	Mission Breath Alcohol Detectors
Blow Bag Used	No	Yes - device may be used with or without blow bag

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

NHTSA/DOT Highway Safety Programs; Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids, (Federal Register/Vol.59, No.147, August 2, 1994/Notices/39382

NHTSA/DOT Highway Safety Programs; Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids, (Federal Register/Vol.73, No.62, March 3, 2008/Notices

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 greater than or equal to the cut-off indicated on the detector.

M. Performance Characteristics (if/when applicable):

The Mission Breath Alcohol Detectors were not eligible for testing by the National Highway Traffic Safety Administration (NHTSA) (Department of Transportation (DOT)). The sponsor performed DOT-like testing using the guidelines found in the August 2, 1994 and March 3, 2008 NHTSA/DOT Model Specifications for Alcohol Screening Devices.

1. Analytical performance:

   a. Precision/Reproducibility:

   The sponsor performed precision and accuracy testing for each of the six cutoffs using a Breath Alcohol Sample Simulator (BASS), which provides an alcohol-in-air test sample with known alcohol concentrations, flow rate and air composition.

   Testing was performed by twelve individuals under five different lighting sources using three lots over three days. The concentrations used were 0% BAC, 50% below the cut-off concentration and 50% above the cut-off concentration. The table below lists the number of devices that resulted in the expected outcome (positive or negative) of the number of devices evaluated.

With Blow Bag

		Tester Used (% BAC)					
	Conc	0.02	0.04	0.05	0.06	0.08	0.10
Daylight	0%	210/210	210/210	210/210	210/210	210/210	210/210
	c/o – 50%	210/210	210/210	210/210	210/210	210/210	210/210
	c/o + 50%	210/210	210/210	210/210	210/210	210/210	210/210
Incandescent	0%	210/210	210/210	210/210	210/210	210/210	210/210
	c/o – 50%	210/210	210/210	210/210	210/210	210/210	210/210
	c/o + 50%	210/210	210/210	210/210	210/210	210/210	210/210

Fluorescent	0%	210/210	210/210	210/210	210/210	210/210	210/210
	c/o – 50%	210/210	210/210	210/210	210/210	210/210	210/210
	c/o + 50%	210/210	210/210	210/210	210/210	210/210	210/210
Mercury Vapor	0%	210/210	210/210	210/210	210/210	210/210	210/210
	c/o – 50%	210/210	210/210	210/210	210/210	210/210	210/210
	c/o + 50%	210/210	210/210	210/210	210/210	210/210	210/210
Sodium Vapor	0%	210/210	210/210	210/210	210/210	210/210	210/210
	c/o – 50%	210/210	210/210	210/210	210/210	210/210	210/210
	c/o + 50%	**0/210**	**85/210**	**89/210**	**108/210**	**125/210**	**160/210**

Without Blow Bag

		Tester Used (% BAC)					
	Concentration	0.02	0.04	0.05	0.06	0.08	0.10
Daylight	0%	210/210	210/210	210/210	210/210	210/210	210/210
	Cutoff – 50%	210/210	210/210	210/210	210/210	210/210	210/210
	Cutoff + 50%	210/210	210/210	210/210	210/210	210/210	210/210
Incandescent	0%	210/210	210/210	210/210	210/210	210/210	210/210
	Cutoff – 50%	210/210	210/210	210/210	210/210	210/210	210/210
	Cutoff + 50%	210/210	210/210	210/210	210/210	210/210	210/210
Fluorescent	0%	210/210	210/210	210/210	210/210	210/210	210/210
	Cutoff – 50%	210/210	210/210	210/210	210/210	210/210	210/210
	Cutoff + 50%	210/210	210/210	210/210	210/210	210/210	210/210
Mercury Vapor	0%	210/210	210/210	210/210	210/210	210/210	210/210
	Cutoff – 50%	210/210	210/210	210/210	210/210	210/210	210/210
	Cutoff + 50%	210/210	210/210	210/210	210/210	210/210	210/210
Sodium Vapor	0%	210/210	210/210	210/210	210/210	210/210	210/210
	Cutoff – 50%	210/210	210/210	210/210	210/210	210/210	210/210
	Cutoff + 50%	**11/210**	**94/210**	**112/210**	**122/210**	**134/210**	**185/210**

This study showed 100% agreement with the expected results for all lighting conditions except sodium vapor, which is typically found in streetlights. The labeling warns users not to read the device under streetlights.

b. Linearity/assay reportable range:

Not applicable. The assay is semi-quantitative and does not report a numerical concentration.

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

These devices are traceable to a commercially available certified alcohol reference solution. These solutions are used to verify the cut-off concentration of the devices during manufacture.

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 samples in their precision study above and no false positive results were produced.

e. Analytical specificity:

Cigarette Smoke. The effect of cigarette smoke study on the device was evaluated with and without blow bags by testing 5 participants per cutoff level who have smoked ½ to 1 cigarette and have not had an alcoholic drink for the last 24 hours. Each participant waited 15 minutes after smoking, then performed the test themselves according to the package insert for each cut-off level in 4 replicates. The devices produced no false positive results under these conditions.

Temperature. The temperature effect on the device was evaluated with and without blow bag using simulated breath sample at +/-50% of the cut-off levels at 5^{o} and 40^{o} C. The BAC breath alcohol concentration in the simulated breath (control air) was verified by an evidential-type breath alcohol detector. The alcohol control gas was introduced into the detector until the blow bag had inflated completely or the sample had been introduced for 12 seconds. The results were then read under fluorescent lighting at 2 minutes according to the package insert. All the samples were tested in 20 replicates. The table below summarizes the results using the blow bag:

Cutoff	Mission Breath Alcohol Detector Results with blow bag			
	5^{o} C		40^{o} C	
	Cutoff – 50%	Cutoff + 50%	Cutoff – 50%	Cutoff + 50%
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
0.10%	20/20 Negative	20/20 Positive	20/20 Negative	20/20 Positive

The results were identical when the study was repeated using testers without blow bags.

Vibration. The effect of vibration on the device was evaluated with and without blow bags using a shake table with a vibration time of 2.5 minutes. After vibration, performance was tested using simulated breath samples at +/-50% of the cut-off levels. The BAC breath alcohol concentration was verified

by an evidentiary breath alcohol device. A summary of device performance after vibration testing is presented in the following table.

Cutoff	Mission Breath Alcohol Detector Results with blow bag	
	Cutoff – 50%	Cutoff + 50%
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
0.10%	20/20 Negative	20/20 Positive

The results were identical when the study was repeated using testers without blow bags.

f. Assay cut-off:

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

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor conducted a consumer study comparing the Mission Breath Alcohol Detector at 0.04% BAC to a quantitative comparator device. Results were collected with and without blow bags. The purpose of the study was to determine if consumers could correctly perform and interpret the test according to the package insert. There were 32 participants who consumed alcohol as part of the study paired with 32 non-drinkers who read the results. Each drinker provided four breath samples over the course of the study for a total of 128 comparisons. There were 30 males and 34 females who participated in the trial. Educational background is as follows:

Education	Elementary	Middle School	High School	College
	2	1	11	50

The non-drinker administered the test to the drinker and then read the results. The drinker then provided another breath sample, which was analyzed using the quantitative device operated by a trained individual. The breath alcohol concentrations ranged from a BAC of 0.000% to 0.127% by the comparator device.

Results using the blowbag and read by laypersons were as follows:

Mission 0.04% Tester Result	Less than cutoff – 60% (<0.016%)	Near cutoff negative (0.016 – 0.040)	Near cutoff positive (>0.040 – 0.064)	High Positive (>0.064%)
Positive	0	20	50	14
Negative	16	28	0	0

Results read without the blowbag and read by laypersons were identical to those with the blowbag.

b. Matrix comparison:

Not applicable. This device is for one sample matrix.

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.