

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

A. 510(k) Number:

k060761

B. Purpose for Submission:

New Device

C. Measurand:

Breath Alcohol

D. Type of Test:

Qualitative

E. Applicant:

Akers Biosciences Inc.

F. Proprietary and Established Names:

BreathScan Alcohol Detectors (0.02, 0.04, 0.05 and 0.08% BAC)

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):

See indications for use below.

2. Indication(s) for use:

The BreathScan Alcohol Detector is an in vitro medical device to qualitatively 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 including 0.02, 0.04, 0.05 and 0.08 percent breath alcohol. The device is used only as a screening device and is only 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 BreathScan Alcohol Detector is a qualitative visually read single-use device. The device contains yellow crystals inside a 2-part glass vessel, which is housed inside a plastic tube. One end of the plastic tube is open for sample collection and immediate testing of human breath for alcohol. The device is available at four different detection levels (0.02, 0.04, 0.05 and 0.08% BAC).

J. Substantial Equivalence Information:

1. Predicate device name(s):

Connectables Alcohol Tester, Connectables, LLC

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

k052448

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Indications for Use	Detect the presence of alcohol in the human breath.	Detect the presence of alcohol in the human breath.
Target Populations	Over the Counter	Over the Counter
Calibration/Accuracy Checks	None required	None required
Anatomical Site	Mouth	Mouth
Test Sample	Human breath	Human breath

Differences		
Item	Device	Predicate
Result	Qualitative	Semi-Quantitative
Interpretation	Visual Color Change	Red, Yellow, and Green LEDs
Instrument system	None	Semiconductor-Oxide Sensor
Measurement Range	Separate devices are pre-calibrated to turn color at different cut-offs: .02%, .04%, .05%, and .08%	Upper limit undefined – any concentration greater than 0.04% will produce red light

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

Department of Transportation/ National Highway Traffic Safety Administration [NHTSA Docket No. 94-004; Notice 2] Highway Safety Programs; Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids

L. Test Principle:

The BreathScan Alcohol Detector contains chemicals that change color in the presence of alcohol in human breath. The detector is squeezed to break the glass vessel which contains the chemically coated yellow crystals. The user blows into the open end of the plastic tube allowing the breath to come in contact with the yellow crystals. A color change from yellow to blue-green will occur if the alcohol in the breath is at or above the detection limit of the device.

M. Performance Characteristics (if/when applicable):

The BreathScan Alcohol Detector was 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 1994 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 four BreathScan Alcohol Detectors (.02, .04, .05 and .08 BAC) 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 43 individuals under five different lighting sources using sixty randomized pre-reacted detectors. The concentrations used were 20 detectors at 0% BAC, 20 at 60% below the cut-off concentration and 20 at 60% above the cut-off concentration. The table below describes the number of devices that resulted in the expected outcome (positive or negative) of the number of devices evaluated.

	Concentration	.02	.04	.05	.08
Fluorescent	0%	200/200	239/240	220/220	200/200
	-60% of cut-off	200/200	240/240	220/220	200/200
	+ 60% of cut-off	200/200	240/240	220/220	200/200
Daylight	0%	200/200	240/240	220/220	200/200
	-60% of cut-off	200/200	240/240	220/220	200/200
	+ 60% of cut-off	200/200	240/240	220/220	200/200
Incandescent	0%	200/200	240/240	220/220	200/200
	-60% of cut-off	200/200	240/240	220/220	200/200
	+ 60% of cut-off	200/200	239/240	220/220	200/200
Sodium Vapor	0%	200/200	240/240	220/220	200/200
	-60% of cut-off	200/200	239/240	220/220	200/200
	+ 60% of cut-off	200/200	240/240	220/220	200/200
Mercury Vapor	0%	200/200	240/240	220/220	200/200
	-60% of cut-off	200/200	240/240	220/220	200/200
	+ 60% of cut-off	200/200	238/240	220/220	200/200
% Agreement		100/100	99.9/99.6	100/100	100/100

b. *Linearity/assay reportable range:*

Not applicable. The assay is a qualitative assay.

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

The device is 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. Non-alcoholic human breath was used as the sample. All of the devices tested except for the .04 detector under Fluorescent lighting, did not produced a false positive when measuring zero concentration samples. The .04 detector showed one false positive result when read under a Fluorescent light.

e. Analytical specificity:

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

Cigarette smoke – An alcohol-free volunteer was asked to smoke approximately one half of a cigarette. The volunteer then performed a breath alcohol reading. The volunteer then smoked another inhalation and repeated test to produce a total of five trials for each cut-off concentration. The BreathScan Alcohol Detector produced no false positives results under these conditions.

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

Cut-off	Breath Scan Results			
	10 °C		40 °C	
	60% below Cut-off	60% above Cut-off	60% below Cut-off	60% above Cut-off
.02	20/20 Negative	20/20 Positive	20/20 Negative	20/20 Positive
.04	20/20 Negative	20/20 Positive	20/20 Negative	20/20 Positive
.05	20/20 Negative	20/20 Positive	20/20 Negative	20/20 Positive
.08	20/20 Negative	20/20 Positive	20/20 Negative	20/20 Positive

Vibration - A total of forty different devices were mounted on a shaketable or rocker for each cut-off concentration for 5 minutes. Using simulated breath (BASS) twenty samples that were 60% below the device cut-off and twenty samples were 60% above the cut-off were tested. The results are presented in the table below:

Cut-off	BreathScan Results	
	60% below Cut-off	60% above Cut-off
.02	20/20 Negative	20/20 Positive

.04	20/20 Negative	20/20 Positive
.05	20/20 Negative	20/20 Positive
.08	20/20 Negative	20/20 Positive

f. *Assay cut-off:*

Each device will produce a blue-green color at or above the following cut-off concentration, .02, .04, .05 and .08 %BAC.

2. Comparison studies:

a. *Method comparison with predicate device:*

The sponsor conducted a consumer study comparing the BreathScan Alcohol Detector .04% BAC to a quantitative comparator device device. The purpose of the study was to determine if consumers could correctly perform and interpret the test according to the package insert. There were 24 paired volunteers (drinker, non-drinker). The reported age range of the volunteers was from below 30 to 60 years of age. There were 18 males and 30 females who participated in the trail. 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 0.00% to 0.144% by the predicate device.

Ninety-three breath alcohol tests were performed and the results are in the table below:

BreathScan .04% Tester Result	Quantitative Results			
	Less than 60% below the Cut-off (<0.016%)	Near Cut-Off Negative (0.016 to 0.040%)	Near Cut-off Positive (>0.040 to 0.064%)	High Positive (>0.064%)
Positive	0	0	15	10
Negative	37	25	5	1

After the study, participants completed a questionnaire about the ease of use of the device:

Question	Strongly Disagree	Disagree	Don't Know	Agree	Strongly Agree
The BreathScan Instructions are easy to understand	0	0	0	9	15
The BreathScan Instructions are not	0	0	0	10	14

difficult to follow					
It is easy to see and understand the BreathScan test results	0	0	3	1	11

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 by this device.

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.