

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

**A. 510(k) Number:**

k102338

**B. Purpose for Submission:**

New device

**C. Manufacturer and Instrument Name:**

Akers Biosciences Inc, BreathScan®PRO

**D. Type of Test or Tests Performed:**

Quantitative

**E. System Descriptions:**

1. Device Description:

The BreathScan Pro consists of a self-contained electronic analyzer, the one time use detectors and an re-useable blow bag. The analyzer is powered by a lithium battery and turns on when the detector is inserted into it. After 2 minutes the analyzer will display the breath alcohol concentration (BAC) to three decimal places. The results are displayed for 10 seconds.

2. Principles of Operation:

The BreathScan Pro Detector consists of a plastic tube which contains an inner glass tube and microparticles (crystals). Through a catalyzed process, these reactive particles form a complex with the biomarker in the breath condensate which causes a color change. The electronic analyzer contains a digital color sensor that is sensitive to red, green and blue regions of the spectrum. Detected signals are serially output of digital data that is converted into the quantitative BAC.

3. Modes of Operation:

This device has only one mode of operation. See section 2 above.

4. Specimen Identification:

There is no mechanism to identify the specimen.

5. Specimen Sampling and Handling:

The user provides a breath sample by exhaling into the detector before insertion into the detector.

6. Calibration:

The device is calibrated at the factory and the calibration is stable for 2000 test results. When 100 tests are left the device will give a low battery alarm. After the 2000 test is run the device will power down. The device is disposed of after 2000 tests.

7. Quality Control:

There are no external quality controls available for this type of device for over-the-counter use.

8. Software:

FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes  X  or No \_\_\_\_\_

**F. Regulatory Information:**

1. Regulation section:

21 CFR § 862.3050, Breath-Alcohol Test System

2. Classification:

Class I, reserved

3. Product code:

DJZ

4. Panel:

91-Toxicology

**G. Intended Use:**

See Indications for use below

1. Indication(s) for Use:

The BreathScan®PRO is an in vitro medical device that quantitatively detects the presence of alcohol in the human breath. The device is used only as a screening device and is an indication of the possible presence of alcohol in the blood of the test subject.

2. Special Conditions for Use Statement(s):

For over-the-counter use

**H. Substantial Equivalence Information:**

1. Predicate Device Name(s) and 510(k) numbers:

Breath Alcohol<sup>v</sup>/®.02 Detection Device, Akers Biosciences Inc.

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

k062971

3. Comparison with Predicate Device:

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Indications for Use	Detect the presence of alcohol in human breath.	Same
Target Populations	Over the Counter	Same
Calibration/Accuracy Checks	None required	Same
Construction	Plastic casa with internal circuit board	Same

<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Result	Quantitative	Qualitative
Battery Life	2000 measurements	1000 measurements
Power source	1 Lithium 9 volt (built in)	2- CR2032 batteries (built in)
Measurement Range	Defined limits, 0.00% to 0.15% (higher levels displayed as >0.15%) BAC	Defined limits, <.02% = Green flashing LED (negative) and ≥ .02% = Red flashing LED (positive)
Display	Digital Read out	Red, Green LEDs

**I. Special Control/Guidance Document Referenced (if applicable):**

Department of Transportation, National Highway Traffic Safety Administration, Model Specifications for Alcohol Screening Devices - Federal Register on March 31, 2008

**J. Test Principle:**

The BreathScan Pro Detector consists of a plastic tube which contains an inner glass tube and microparticles (crystals). Through a catalyzed process, these reactive particles form a complex with the breath condensate which causes a color change. The electronic analyzer contains a digital color sensor that is sensitive to red, green and blue regions of the spectrum. Detected signals are then converted into the quantitative BAC.

**K. Performance Characteristics:**

1. Analytical Performance:

*a. Accuracy:*

The sponsor performed a consumer study using the BreathScan Pro to determine if consumers could correctly use and interpret the device using only the package insert and to compare the results to the predicate device. There were 62 paired comparisons and the volunteers ranged in age from 21 to over 61 years of age. Each participant took their breath alcohol reading with the BreathScan Pro and immediately were administered a breath alcohol test using the predicate device operated by a trained individual. The non-drinker had the detector read by the analyzer and recorded the results. The breath alcohol concentrations ranged from BAC of 0.000% to 0.150%.

Linear regression analysis of the data showed a slope 0.882, y-intercept of 0.004 and a correlation coefficient of 0.855. After the study, participants were asked about the ease of use and interpretation. Participant demographics and responses to the survey are presented below:

<b>Participant Information</b>	
<b>Gender #</b>	
<b>M</b>	<b>29</b>
<b>F</b>	<b>33</b>
<b>Total</b>	<b>62</b>

Questions:

Question	Strongly Disagree	Disagree	Don't Know	Agree	Strongly Agree	Yes/No	True/False
The instructions are easy to understand				30	32		
The instructions are NOT difficult to follow				27	32		
It is easy to see and understand the test results		1		23	38		
BreathScan PRO is a screening test							58/4
Can you take a reading immediately after drinking?						2/60	
Positive results should be confirmed							60/2
If I have been drinking, I can test myself							11/51

*b. Precision/Reproducibility:*

The sponsor performed a “DOT-Like” precision and accuracy study. The testing followed the NHTSA requirements (referred to as Model Specifications) which consist of 20 trials at a Blood Alcohol Concentration (BAC) of 0.008, 20 trials at a BAC of 0.032, and 20 trials at a BAC of 0.000. The sponsor also conducted testing at +/- 60% for each of the following cutoff concentration, .02%, .05%, .08%, .12%. Blood Alcohol Concentrations are simulated in breath 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 acceptance criteria for the Model Specifications are: not more than one negative result at +60% BAC cutoff, not more than one positive result at -60% BAC cutoff, and not more than one negative greater than zero and no positives at 0.000 BAC.

The results are presented in the table below:

Cut-off	BreathScan®PRO Results (DOT/NHTSA study)		
	Human Breath (Blank)	60% below cutoff (.008%)	60% above cutoff (.032%)
.02%	20/20 Negative	20/20 Negative	20/20 Positive
	BreathScan®PRO Results		
	Human Breath (Blank)	60% below cutoff	60% above cutoff
.02%	20/20 Negative	20/20 Negative	20/20 Positive
.05%	20/20 Negative	20/20 Negative	20/20 Positive
.08%	20/20 Negative	20/20 Negative	20/20 Positive
.12%	20/20 Negative	20/20 Negative	20/20 Positive

*c. Linearity:*

This BreathScan®PRO will report concentrations from 0.00 to 0.15% BAC. However, DOT Model Specifications require accuracy and precision testing up to a concentration of 0.032 only; therefore true linearity over the entire measuring range of the device was not evaluated. This device met all applicable NHTSA requirements for precision and accuracy as described above.

*d. Carryover:*

Carryover studies are not required by NHTSA and were not performed using these devices.

*e. Interfering Substances:*

The DOT Model Specifications require testing with cigarette smoke to assess any possible interference. Five trials are required at 0.000 BAC. An alcohol free individual who smokes cigarettes is appropriate for this trial. The subject is asked to smoke approximately one half of a cigarette. Within one minute after smoking, or after a waiting period specified in the manufacturer's instructions, the subject performs the breath alcohol test according to the manufacturer's instructions. The subject is then asked to smoke another inhalation and repeat the test to produce a total of five trials. The acceptance criterion for this trial is: no false positive results.

The BreathScan®PRO had no false positive results.

Other potential interferents were not evaluated with this device.

2. Other Supportive Instrument Performance Data Not Covered Above:

a. Limit of Detection

The DOT Model Specifications do not specifically address the detection limit of breath alcohol devices. However, the devices must be tested at a BAC of zero (blank reading) to assess the possibility of false positives. This consists of 20 trials under normal laboratory conditions at a BAC of 0.000. Non-alcoholic human breath is to be used as the sample. For devices capable of providing a reading of greater than 0.000 BAC and less than 0.020 BAC, the acceptance criterion is: not more than one such result. These devices had no false positives in this trial.

b. Temperature

The DOT Model Specifications require testing at 10 and 40° C to assess any possible effects of temperature. At 10°C 20 trials are required at 0.008 BAC and 20 trials are required at 0.032 BAC. Acceptance criteria are: not more than one positive result at 0.008 BAC and not more than one non-positive result at 0.032 BAC. The sponsor also conducted testing at the following temperatures, -15° C and 50° C. Twenty trials were conducted +/- 60% for each of the following cutoff concentration, .02%, .05%, .08%, 0.12%. Acceptance criteria are: not more than one positive result at -60% of each cutoff and not more than one non-positive result at +60% of each cutoff. The device had no positive results at -60% of each cutoff and no negative results at +60% of each cutoff.

c. Vibration

The DOT Model Specifications require vibration testing to assess any possible vibrational effects. 20 trials are required at 0.008 BAC and 0.032 BAC. Acceptance criteria are: not more than one positive result at 0.008 BAC and not more than one non-positive result at 0.032 BAC. The sponsor also conducted testing at +/- 60% for each of the following cutoff concentration, .02%, .05%, .08%, 0.12%. Acceptance criteria are: not more than one positive result at -60% of each cutoff and not more than one non-positive result at +60% of each cutoff. The devices had no positive results at -60% of each cutoff and no negative results at +60% of each cutoff.

d. Cutoff

Not applicable

**L. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**M. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.