

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

A. 510(k) Number:

k062971

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:

Breath Alcohol Check .02 detection system
BreathScan .02 Breath Alcohol detection system

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

2. Indication(s) for use:

The Breath Alcohol Check .02 Detection System and BreathScan .02 Breath Alcohol Detection System are *in vitro* medical devices that qualitatively detect the presence of alcohol in the human breath. The test system detects equal to or greater than 0.02 percent breath alcohol. The system 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 Breath Alcohol Check .02 and BreathScan .02 Breath Alcohol detection systems are qualitative tests for the detection of alcohol in human breath at concentrations of 0.02% and above. Each system employs the use of lot specific, one-time use detectors, previously cleared under k060761. The detectors contain yellow crystals that change color when exposed to alcohol vapors from human breath. The Breath Alcohol Check .02 and BreathScan .02 electronic analyzers are used to read the charged detectors. The internal design of the analyzers is the same with the only difference being how the detector is positioned or inserted into the analyzer.

The test kit contains either the Breath Alcohol Check .02 or BreathScan .02 electronic analyzer, 25 detectors (each for one-time use), and 3 plastic bags (use is optional for the BreathScan .02 test system). The plastic bag helps ensure that adequate breath is blown into the detector. Each analyzer is designed to be used with a specific lot of detectors.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Connectables Alcohol Tester

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

k052448

3. Comparison with predicate:

| Similarities | | |
|-----------------------------|--|--|
| Item | Device | Predicate |
| Indications for use | Detect the presence of alcohol in human breath Over the counter use | Detect the presence of alcohol in human breath Over the counter use |
| Calibration/accuracy checks | None required | None required |
| Interpretation of result | Red or green LED | Red, yellow, or green LED |

| Differences | | |
|-------------------|---|--|
| Item | Device | Predicate |
| Measurement range | Defined limit, breath alcohol concentration <0.02% = green flashing LED (negative) and ≥0.02% red flashing LED (positive) | Any breath alcohol concentration >0.04%= red light (positive) |

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, published in the Federal Register on August 2, 1994

L. Test Principle:

The previously cleared detector unit (k060761) 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 takes a

deep breath and blows into the detector for approximately 12 seconds, with one continuous blow. A plastic bag, supplied with the test kit, is attached to the opposite end of the detector. Use of the plastic bag is optional for the BreathScan test system. The bag will fully inflate when sufficient breath has been blown into the detector. The bag is then removed from the detector and can be retained for future use. The detector is shaken vigorously for 2-3 seconds and then incubated for 2 minutes. The detector is then placed in either the Breath Alcohol Check .02 analyzer or the BreathScan .02 analyzer. The analyzer automatically turns on and reads the color of the crystals in the detector. The crystals change to a blue-green color if alcohol is present in the breath. Lights will flash instantaneously, with red light indicating a breath alcohol concentration $\geq 0.02\%$ or a green light indicating a breath alcohol concentration $< 0.02\%$.

M. Performance Characteristics (if/when applicable):

The Breath Alcohol Check .02 detection system was tested by the U.S. Department of Transportation (DOT), National Highway Traffic Safety Administration (NHTSA) and was found to meet the requirements of the specifications found in the DOT/NHTSA Model Specifications for Alcohol Screening Devices.

1. Analytical performance:

a. Precision/Reproducibility:

The precision and accuracy of the Breath Alcohol Check .02 detection system was tested by DOT/NHTSA in accordance with the standard listed under Section K of this document. The following tests were performed: 20 trials at a Blood Alcohol Concentration (BAC) of 0.008 and 20 trials at BAC of 0.032. The DOT/NHTSA acceptance criteria are: not more than one positive result at BAC 0.008 (-60% of the device cut-off) and not more than one negative result at BAC 0.032 (+60% of the device cut-off). The Breath Alcohol Check .02 detection system had no positive results at 0.008 and no negative results at 0.032.

The precision and accuracy of the BreathScan .02 breath alcohol detection system was tested in a "DOT-like" testing protocol by the sponsor. Forty (40) pre-reacted detectors with simulated breath alcohol samples were tested and included 20 tests at a BAC 0.008 and 20 at BAC 0.032. The sponsor's acceptance criteria are: not more than one positive result at BAC 0.008 (-60% of the device cut-off) and not more than one negative result at BAC 0.032 (+60% of the device cut-off). The BreathScan .02 alcohol detection system had no positive results at 0.008 and no negative results at 0.032.

b. Linearity/assay reportable range:

Not applicable

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

The devices are traceable to a commercially available certified alcohol reference standard solution at a breath alcohol concentration of 0.02%. The solution is used to calibrate the Breath Alcohol Check .02 and BreathScan .02 Breath Alcohol analyzers during manufacture.

d. *Detection limit:*

DOT/NHTSA guidelines do not specifically address the detection limit of breath alcohol devices but require testing of samples at BAC 0.0 (blank reading). The sponsor performed studies using 20 simulated alcohol-free breath charged detectors and read the detectors with both the Breath Alcohol Check .02 and the BreathScan .02 detection systems. The sponsor's acceptance criterion was none of the blank samples should produce a positive result.

None of the 20 blank samples read by either the Breath Alcohol Check .02 analyzer or BreathScan .02 analyzer gave positive results.

e. *Analytical specificity:*

The sponsor performed studies to evaluate the potential interference of cigarette smoke, temperature, and vibration on results using Breath Alcohol Check .02 and BreathScan .02 breath alcohol test systems.

Cigarette smoke: An alcohol-free volunteer was asked to smoke approximately one half of a cigarette and then perform a breath alcohol test. The volunteer then inhaled the cigarette four more times and performed the breath alcohol test after each inhalation. None of the tests yielded a positive result on either the Breath Alcohol Check .02 or BreathScan .02 detection systems.

Temperature: The sponsor stored test kits containing Breath Alcohol Check .02 and BreathScan .02 analyzers, breath alcohol detectors, blow bags, and test instructions at both 10°C and 40°C. Then twenty detectors from each kit and storage temperature were charged with simulated breath at 60% below the cut-off and 60% above the cut-off. The detectors were then read on the respective Breath Alcohol Check .02 and BreathScan .02 analyzers. The sponsor's acceptance criteria were no more than one positive result for test samples 60% below the cut-off and no more than one negative result for test samples 60% above the cut-off. The results are summarized in the following table:

| | 10°C | | 40°C | |
|--------------------------|-------------------|-------------------|-------------------|-------------------|
| | 60% below Cut-off | 60% above Cut-off | 60% below Cut-off | 60% above Cut-off |
| Breath Alcohol Check .02 | 20/20 Negative | 20/20 Positive | 20/20 Negative | 20/20 Positive |
| BreathScan .02 | 20/20 Negative | 20/20 Positive | 20/20 Negative | 20/20 Positive |

Vibration: The sponsor mounted test kits containing Breath Alcohol Check .02 and BreathScan .02 analyzers, breath alcohol detectors, blow bags, and test instructions on a shaketable or rocker for 5 minutes. Then twenty detectors from each kit were charged with simulated breath at 60% below the cut-off and 60% above the cut-off. The detectors were then read on both the Breath Alcohol Check .02 and BreathScan .02 detection systems. The sponsor's acceptance criteria were no more than one positive result for test samples 60% below the cut-off and no more than one negative result for test samples 60% above the cut-off. The results are summarized in the following table:

| | Vibration | |
|--------------------------|-------------------|-------------------|
| | 60% below Cut-off | 60% above Cut-off |
| Breath Alcohol Check .02 | 20/20 Negative | 20/20 Positive |
| BreathScan .02 | 20/20 Negative | 20/20 Positive |

f. Assay cut-off:

Breath samples with breath alcohol concentration $\geq 0.02\%$ will result in a red light on either the Breath Alcohol Check .02 or BreathScan .02 analyzer. Breath samples with breath alcohol concentration $< 0.02\%$ will result in a green light.

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor conducted a consumer study to test the ability of lay users to perform the test using only written test instructions and obtain accurate results, when compared to a quantitative method.

Twenty pairs of adults participated in the study, one drinker and one non-drinker. The participants were demographically diverse with respect to age,

gender, and level of education. The “drinker” ingested an alcoholic beverage and the “non-drinker” assisted the drinker in performing the breath alcohol test using the Breath Alcohol Check .02 and BreathScan .02 detection systems. The “drinker” was also tested with an evidentiary method by a trained professional.

The results of the study are summarized in the following tables:

| | Evidentiary Breath Test Results | | | |
|---------------------------------|--|---|--|--------------------------|
| Breath Alcohol Check .02 Result | Less than 60% below the Cutoff < 0.008%) | Near Cut-off Negative (0.008 to 0.020%) | Near Cut-off Positive (>0.020 to 0.032%) | High Positive (> 0.032%) |
| Positive | 0 | 1 | 8 | 11 |
| Negative | 22 | 3 | 0 | 0 |

| | Evidentiary Breath Test Results | | | |
|-----------------------|--|---|--|--------------------------|
| BreathScan .02 Result | Less than 60% below the Cutoff < 0.008%) | Near Cut-off Negative (0.008 to 0.020%) | Near Cut-off Positive (>0.020 to 0.032%) | High Positive (> 0.032%) |
| Positive | 0 | 1 | 8 | 11 |
| Negative | 22 | 3 | 0 | 0 |

At the conclusion of testing the study participants were asked to complete a survey for each detection system that was used. In summary, the participants reported that the Breath Alcohol Check .02 and BreathScan .02 detection system instructions were easy to understand and not difficult to follow and that the test results were easy to see and understand. All participants understood that the detection systems were only screening tests and that positive results should be confirmed.

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:

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.