

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

A. 510(k) Number:

k072953

B. Purpose for Submission:

New Device

C. Measurand:

Breath Alcohol

D. Type of Test:

Qualitative

E. Applicant:

Redline Products (Pty) Ltd

F. Proprietary and Established Names:

Redline disposable Alcohol Breath Tester (0.02, 0.04, 0.05, 0.08 and 0.10% BAC)

G. Regulatory Information:

| Product Code | Classification | Regulation Section | Panel |
|--------------|-------------------|--------------------|----------------|
| DJZ | Class I, reserved | 862.3050 | 91, Toxicology |

H. Intended Use:

1. Intended use(s):

See indication for use below.

2. Indication(s) for use:

The Redline Alcohol Tester 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 tester is available in several calibrations: 0.02%, 0.04%,

0.05%, 0.08% and 0.10% Blood Alcohol Concentration equivalents in the breath. The device is used as a screening device only and provides an indication of the presence and amount of alcohol in the blood of the test subject. Correlation between breath alcohol content and blood alcohol content depends on many variables. Redline is not intended to legally determine blood alcohol presence, level or inference of intoxication.

3. Special conditions for use statement(s):

For Over the Counter use.

4. Special instrument requirements:

Not applicable.

I. Device Description:

The Redline Breath Alcohol Tester is a qualitative visually read single-use device. The device is a glass tube which contains yellow crystals held in place by two metal sieves and at either end of the tube is a portion of amorphous silicagel particles which act as a protective barrier which are discarded before use. The glass tube is closed at both ends with plastic snap-off caps. The sample is collected into a fixed volume plastic bag. Once inflated the tester is inserted into the neck of the bag. The breath is squeezed from the bag through the device to determine the alcohol concentration. The device is available at five different detection levels (0.02, 0.04, 0.05, 0.08 and 0.10% BAC).

J. Substantial Equivalence Information:

1. Predicate device name(s):

Breathscan Alcohol Detector, Akers Biosciences, Inc

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

k060761

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 |

| Similarities | | |
|------------------------------------|---------------|---------------|
| Item | Device | Predicate |
| Calibration/Accuracy Checks | None required | None required |
| Anatomical Site | Mouth | Mouth |
| Test Sample | Human breath | Human breath |

| Differences | | |
|------------------------------|---|---|
| Item | Device | Predicate |
| Result Interpretation | Extent of color change | Intensity of color change |
| Blowing time | 12 seconds | 10 seconds |
| Collection device | Plastic bag | none |
| Measurement Range | Separate devices are pre-calibrated to turn color at different cut-offs: .02%, .04%, .05%, and .08% and 0.10% | Separate devices are pre-calibrated to turn color at different cut-offs: .02%, .04%, .05%, and .08% |

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

None referenced.

L. Test Principle:

The Redline Breath Alcohol Tester contains chemicals that change color in the presence of alcohol in human breath. The plastic ends of the tester are snapped off and the white silicagel particles are removed. After the user blows into the plastic bag the tester is then connected by inserting it in the neck of the bag. The breath sample is squeezed from the bag into the tester allowing the sample to come in contact with the chemically coated yellow crystals. Each device has a red line which indicates the cutoff concentration for each device. The devices will detect a minimum color change from yellow to green of 0.02% BAC indicating the presence of alcohol. If the color change reaches the red line on the device, the alcohol in the breath is at the detection limit specified on the device.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The sponsor evaluated the precision and accuracy for each of the five Redline Breath Alcohol Testers (0.02, 0.04, 0.05, 0.08 and 0.10 % BAC) using a Breath Alcohol Sample Simulator (BASS), which provides an alcohol-in-air

test sample with know alcohol concentrations, flow rate and air composition.

Testing was performed by 10 individuals under five different lighting sources using 60 randomized pre-reacted testers. The concentrations used were 20 testers at 0% BAC, 20 at 60% below the cut-off concentration and 20 at 60% above the cut-off concentration. The table below shows the number of devices that resulted in the expected outcome (negative or positive) of the number of devices evaluated.

| | Concentration | .02 | .04 | .05 | .08 | .10 |
|---------------|------------------|----------------|----------------|----------------|----------------|----------------|
| Fluorescent | 0% | 200/200 | 200/200 | 200/200 | 200/200 | 200/200 |
| | -60% of cut-off | 200/200 | 200/200 | 200/200 | 200/200 | 200/200 |
| | + 60% of cut-off | 200/200 | 200/200 | 200/200 | 200/200 | 200/200 |
| Daylight | 0% | 200/200 | 200/200 | 200/200 | 200/200 | 200/200 |
| | -60% of cut-off | 200/200 | 200/200 | 200/200 | 200/200 | 200/200 |
| | + 60% of cut-off | 200/200 | 200/200 | 200/200 | 200/200 | 200/200 |
| Incandescent | 0% | 200/200 | 200/200 | 200/200 | 200/200 | 200/200 |
| | -60% of cut-off | 200/200 | 200/200 | 200/200 | 200/200 | 200/200 |
| | + 60% of cut-off | 200/200 | 200/200 | 200/200 | 200/200 | 200/200 |
| Sodium Vapor | 0% | 200/200 | 200/200 | 200/200 | 200/200 | 200/200 |
| | -60% of cut-off | 199/200 | 198/200 | 199/200 | 198/200 | 198/200 |
| | + 60% of cut-off | 200/200 | 200/200 | 200/200 | 200/200 | 200/200 |
| Mercury Vapor | 0% | 200/200 | 200/200 | 200/200 | 200/200 | 200/200 |
| | -60% of cut-off | 199/200 | 198/200 | 199/200 | 199/200 | 199/200 |
| | + 60% of cut-off | 200/200 | 200/200 | 200/200 | 200/200 | 200/200 |
| % Agreement | | 99.9/100 | 99.8/100 | 99.9/100 | 99.8/100 | 99.8/100 |

b. Linearity/assay reportable range:

Not applicable. This assay is a qualitative assay.

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

The concentrations are prepared from commercially available solutions and are verified on certified evidential breath alcohol tester. 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 did not produce a false positive when measuring zero concentration samples.

e. Analytical specificity:

The sponsor performed the following studies for each cut-off concentration (0.02, 0.04, 0.05, 0.08 and 0.10% BAC) to evaluate the potential interference on the test results from cigarette smoke, temperature and vibration.

Cigarette smoke – Five alcohol-free volunteers were asked to conduct four breath alcohol tests for each device cut-off concentration while smoking a cigarette. The testing was spread out to cover the duration of time it took to smoke a complete cigarette. The Redline Alcohol Tester 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 | Redline Alcohol Tester 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 |
| .10 | 20/20 Negative | 20/20 Positive | 20/20 Negative | 20/20 Positive |

Vibration - A total of forty different devices for each cut-off concentration were placed in a box and mounted on a vibration table 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 | Redline Alcohol Tester 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 |
| .10 | 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, .08 and .10%BAC.

2. Comparison studies:

a. *Method comparison with predicate device:*

The sponsor conducted a consumer study comparing the Redline Breath Alcohol Tester 0.05% BAC to a quantitative comparator 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 20 paired volunteers (drinker, non-drinker). The reported age range of the volunteers was from 20 to 60 years of age. There were 12 males and 8 females who participated in the trial. The non-drinker administered the test to the drinker and then read the results. The drinker then immediately 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 <0.03% to >0.07% by the predicate device.

One hundred breath alcohol tests were performed and the results are in the table below:

| Redline Alcohol 0.05% Tester Result | Quantitative Results | | | | | |
|-------------------------------------|----------------------|--------------|------------------------------------|------------------------------------|--------------|-------------|
| | Less than 0.03% | 0.03-0.04% | Near Cut-off Negative (0.04%-.05%) | Near Cut-off Positive (.05%-0.06%) | 0.06%-0.07% | Above 0.07% |
| | >40% below | 20-40% below | | | 20-40% above | >40% above |
| Positive | 0 | 0 | 2 | 18 | 18 | 16 |
| Negative | 16 | 19 | 10 | 1 | 0 | 0 |

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 Redline Instructions are easy to understand and follow | 0 | 0 | 0 | 7 | 13 |
| It is easy to see and read the Redline results | 0 | 0 | 0 | 8 | 12 |

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.