

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

A. 510(k) Number:

k060343

B. Purpose for Submission:

New Device for the US market.

C. Measurand:

Breath Alcohol

D. Type of Test:

Quantitative (Oxide Semiconductor Alcohol Sensor)

E. Applicant:

Sentech Korea Corp.

F. Proprietary and Established Names:

AlcoScan AL-6000 Breath Alcohol Tester

G. Regulatory Information:

1. Regulation section:

21 CFR 862.3050

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 AL-6000 Breath Alcohol Tester is a screening device for the rapid detection of alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcoholic intoxication.

3. Special conditions for use statement(s):

For Over-the-counter use.

4. Special instrument requirements:

AL-6000 Breath Alcohol device

I. Device Description:

The AL-6000 Breath Alcohol Test is a self-contained unit with a breath pipe at the top of the unit. The window display has a ready, warn, and a battery low indicator and displays alcohol concentration in increments of 0.01%. If the breath alcohol concentration (BAC) is between the ranges of 0.00% to 0.04%, there is not change shown on the device. However, if the BAC ranges between 0.05% to 0.39%, the alcohol level warning indicator will flash and the unit will beep. The following occurs based on BAC:

Your Reading	Your Range	Description	Device Behavior
0.00% to 0.01%	Safe range.	Little/no alcohol intake.	(No special warnings.)
0.02% to 0.04%	Moderate range.	Increased alcohol intake.	(No special warnings.)
0.05% and over	Warning range.	Ability to drive may be impaired.	Flashing WARN indicator and repeating beep.

The unit can be powered by two 1.5V “AA” batteries. The warning light has three other displays: Flo, Cal and Bat. Flo. is a warning for insufficient breath sample. Cal. display to notify the user that calibration is needed. Bat. notifies the user of low battery power. An on/off toggle power switch is located on the top of the device.

J. Substantial Equivalence Information:

1. Predicate device name(s):

AlcoMate CA2000

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

k041334

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	Screening device for the rapid detection of alcohol in human breath. Measurements obtained are used in the diagnosis of alcoholic intoxication.	Same
Measuring Range	0.00% to 0.40%	Same
DOT Approved	Yes	Same
Warm-up time	20 seconds	20 seconds
Display	3 digit LED	Same
Sensor type	Semi-conductor	Semi-conductor oxide

Differences		
Item	Device	Predicate
Size	5 ½" x 3" x 2"	5 ½" x 3 ¼" x 1"
Weight	117 grams	171 grams
Power Source	Two 1.5V AA batteries	9V Alkaline battery

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

Department of Transportation National Highway Traffic Safety Administration;
Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids.
Docket No. 94-004.

L. Test Principle:

The Alcoscan AL-6000 is designed to measure the breath alcohol concentration of deep lung air. This concentration is automatically converted to blood alcohol concentration using the relationship established by Henry's law.

The device user is instructed to blow into the breath pipe for 5 seconds to obtain a deep lung breath sample, taking care not to block the breath out opening. A semiconductor sensor is sensitive to changes in conductivity due to the presence of alcohol in the breath. This change in conductivity/resistance due to the alcohol is quantitated and converted to a percent concentration of alcohol.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The precision and accuracy of this device was demonstrated through testing required by the US Department of Transportation. For precision and accuracy, 20 trials at a Blood Alcohol Concentration (BAC) of 0.008, 20 trials at a BAC of 0.032, and 20 trials (of a blank reading) at a BAC of 0.000. 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 sponsor's acceptance criteria are: not more than one negative result at 0.032 BAC, not more than one positive result at 0.008 BAC, and not more than one negative greater than zero and no positives at 0.000 BAC. NOTE: for the purposes of this study, a BAC of .020 is used to distinguish a positive from a negative result. The AL-6000 device had no negatives at 0.032 BAC, no positives at 0.008 BAC, and no positives or non-zero negatives at 0.000 BAC.

b. *Linearity/assay reportable range:*

This device will report concentrations from 0.00 to 0.40%.

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

This device is traceable to a commercially available certified alcohol reference solution at a concentration of 0.06 BAC. This solution is used to calibrate the devices during manufacture.

d. *Detection limit:*

The device was tested at a BAC of zero (blank reading) to assess the possibility of false positives. Data is summarized in the precision section above.

To evaluate the ability of the device to signal users with BAC levels over 0.05% by beeping and blinking, a study were conducted with 5 samples (0.05 to 0.07) on one hundred devices (n=500). All of the devices signaled a beep and light as manufactures states in their package insert.

e. *Analytical specificity:*

Five breath samples including cigarette smoke at 0.000 BAC were tested. An alcohol-free individual who smokes cigarettes was used for this trial. The subject was asked to smoke approximately one half of a cigarette. Within one

minute after smoking, the subject performed the breath alcohol test according to the manufacture's instructions. The subject then smoked another inhalation and repeated the test to produce a total of five trials. The sponsor's acceptance criteria for this trial are that no positive results would be obtained. The Alcoscan AL-6000 device had no false positives in this trial. Other potential interferences were not evaluated with this device.

Temperature:

The Alcoscan AL-6000 was tested at 10 and 40° C to assess any possible effects of temperature.

At 10° C, 20 separate trials at 0.008 BAC and 0.032 BAC were performed. The sponsor's acceptance criteria are that not more than one positive result at 0.008 BAC and not more than one non-positive result at 0.032 BAC. The Alcoscan AL-6000 had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC. At 40° C, the requirements and results were identical.

Vibration:

The Alcoscan AL-6000 was tested to assess any possible vibration effects at 10 to 30 hertz and 30 to 60 hertz.

Twenty trials were performed at 0.008 BAC and 0.032 BAC. The sponsor's acceptance criteria are that not more than one positive result at 0.008 BAC and not more than one non-positive result at 0.032 BAC. The Alcoscan AL-6000 device had no positive result at 0.008 BAC and no non-positive results at 0.032 BAC.

f. Assay Cutoff:

For purposes of performance testing, a BAC cutoff of 0.020 was used to distinguish positive from negative samples. The sponsor states "Driving alcohol in ANY amount may impair the ability to drive. There is no safe level of alcohol intake before driving. Don't drink and drive".

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor conducted a consumer study comparing the AL-6000 to the predicate device, Alcomate CA2000. The purpose of the study was to determine if consumers could correctly operate and interpret the device using only the supplied users' manual and to compare the results to the predicate device. Study subjects included seventy males and forty-seven females (n=117) between the ages of 18 to 69.

Each participant took their own BAC readings with the AL-6000 and recorded the results. Immediately following the self reading, a survey administrator conducted and obtained a BAC reading using the predicate device. BAC readings ranged from 0.00 to 0.31 (both devices). Linear regression analysis of the data shows a slope of 0.98, a y-intercept of 0.001 and a correlation constant of 0.98.

After the study, participants were asked questions about the ease of use of the device:

Question	Strongly Agree	Somewhat Agree	Neither Agree Nor Disagree	Somewhat Disagree	Strongly Disagree
I understood how the use AL6000 after reading the labeling and manual.	76	37	2	1	1
I was able to operate the AL6000 easily.	77	33	4	2	1
I was able to operate the AL6000 easily because of the instructions and labeling provided.	73	36	4	3	1
I was able to easily understand and interpret the test results displayed by the AL6000.	76	36	3	2	0

The Flesch-Kincaid reading ease and grade level were 56.7 and 8.4, respectively.

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.