

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

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

k041334

**B. Purpose for Submission:**

New Device for the US Market (This device has met the US Department of Transportation requirements for breath alcohol devices)

**C. Manufacturer and Instrument Name:**

Sentech Korea Corp., AlcoScan AL-2500

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

Quantitative (Oxide Semiconductor Alcohol Sensor)

**E. System Descriptions:**

1. Device Description:

The AlcoScan AL-2500 is a self-contained unit with semiconductor-based gas sensor, 3 digit LCD display, and power button. The 3 digit LCD display window displays the alcohol concentration in increments of 0.01%. The display is also capable of displaying “Wait”, “Low Battery”, “Calibration”, “Warn” states, corresponding to warm up, low battery, calibration, and warn conditions, respectively. If the alcohol concentration is greater than or equal to 0.05%, the “WARN” light will be displayed on the unit. The unit is powered by two AA batteries. An on/off power switch on the front of the unit toggles the unit on and off.

2. Principles of Operation:

The sample is analyzed by a semiconductor-based gas sensor in order to calculate Breath Alcohol Concentration (BrAC), which is then converted to an equivalent Blood Alcohol Concentration (BAC).

The STK3100 semiconductor sensor consists primarily of a sensing layer and heating element, which is formed by an n-type semiconductor powder and heater, respectively. When the heater is powered in clean air, oxygen molecules in the air trap electrons in the semiconducting material after which they are chemically absorbed on the surface of the powder particles. When the STK3100 is exposed to ethanol vapor, the absorbed oxygen ( $O^-$  or  $O_2^-$ ) reacts with the gas and is reduced. By this reaction, the electrons trapped by the oxygen are released and flow through the semiconductor, which means that resistance decreases and electrical conductivity increases.

This method of operation was used in the predicate device (AlcoMate CA2000).

3. Modes of Operation:  
Modes of operation include “Concentration”, “Wait”, “Low Battery”, “Calibration”, “Warn” states, corresponding to warm up, reading the BAC concentration, indicating low battery, calibration mode, and warning conditions, respectively.
4. Specimen Identification:  
BAC is calculated on a per-use basis.
5. Specimen Sampling and Handling:  
The device takes a breath sample of at least (3) seconds in order to capture an accurate “deep-lung air” sample.
6. Calibration:  
Manufacturer recommends recalibration of the AlcoScan AL-2500 every six months to one year to maintain accuracy. Calibration is performed by opening the device and initiating the calibration mode, then blowing/spraying a prepared 0.04% BAC (0.40g/L BAC or 0.20mg/L BrAC over the sensor for 2 seconds. If the device is to be calibrated by the user, the manufacturer strongly recommends that a high quality breath alcohol tester such as police enforcement equipment or better be used to ensure that an ethanol solution is the proper concentration, when prepared by the consumer.
7. Quality Control (QC):  
In order to ensure that the device functions properly, the manufacturer instructs the user to:
  - a. Wait at least 20 minutes after eating or drinking before testing.
  - b. Avoid testing in high wind or enclosed spaces.
  - c. Do not blow smoke, saliva, or other contaminants into the mouthpiece.
  - d. Keep out of extreme temperatures.
  - e. Recommendation of professional recalibration of the device every six months to one year.
8. Software:  
The sensor contained in the AL-2500 detects alcohol by associating specific voltage ranges to corresponding levels of alcohol. The data is passed as a simple analog signal to an embedded CPU which converts the signal to a digital signal. This digital reading is displayed by the LCD module as a BAC index (in %). All processing is done by the embedded CPU.

**F. Regulatory Information:**

1. Regulation section:  
21 CFR section 862.3050, Breath-alcohol test system.
2. Classification:  
Class I

3. Product code:  
DJZ
4. Panel:  
Chemistry (75)

**G. Intended Use:**

1. Indication(s) for Use:  
The AL-2500 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.
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:  
AlcoMate CA2000 Digital Alcohol Detector, k041334
2. Comparison with Predicate Device:

<b>Similarities</b>		
Item	Device	Predicate
Method	Breath alcohol concentration to BAC	Breath alcohol concentration to BAC
Measurement Range	0.00% to 0.40%	0.00% to 0.40%
Measurement Accuracy	+/-0.01 at 0.10% BAC	+/-0.01 at 0.10% BAC
Sensor Type	Semiconductor oxide sensor	Semiconductor oxide sensor
Certification	DOT / NHTSA	DOT / NHTSA
Practitioner use	Over-The-Counter	Over-The-Counter
Construction	Circuit board housed in plastic casing	Circuit board housed in plastic casing
Warmup Time	About 20 seconds	About 20 seconds
Display	3-digit LCD	3-digit LCD

<b>Differences</b>		
Item	Device	Predicate
Power Source	2 (1.5V each) AA alkaline batteries	9V alkaline battery
Testing Capacity	Approx. 200-300 (on 2 batteries)	Approx. 300 (on 1 battery)
Construction	No mouthpiece	Has mouthpiece
Dimensions	5" x 3 1/4" x 1"	4" x 1 1/2" x 1"
Weight	171 g	85 g

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

- a. 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
- b. Electromagnetic Compatibility directive 89/336/EEC amended by the Directive 93/68/EEC
- c. EN 61326:1997+A1+A2, Electrical equipment for measurement, control, and laboratory use – EMC requirements:
  - i. EN 55022:1998+A1, Radiated Emission
  - ii. EN 61000-4-2:1995+A1+A2, Electrostatic Discharge
  - iii. EN 61000-4-3:1996+A1+A2, Electromagnetic Field

**J. Performance Characteristics:**

1. Analytical Performance:

a. *Accuracy:*

The precision and accuracy of this device has previously been demonstrated through testing required by the US Department of Transportation. For precision and accuracy, these requirements (referred to as Model Specifications) 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. 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 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 0.020 is used to distinguish a positive from a negative result. The AL-2500 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. *Precision/Reproducibility:*

See section a. above.

c. *Linearity:*

This device will report concentrations from 0.00 to 0.40%. However, DOT Model Specifications require accuracy and precision testing at concentrations of 0.008 and 0.032 only; therefore true linearity was not evaluated. This device demonstrated acceptable performance according to the DOT Model Specifications as described above.

d. *Traceability (controls, calibrators, or method):*

This device uses an algorithm to convert deep lung breath alcohol concentration to blood alcohol concentration.

e. *Detection limit:*

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 using fluorescent light 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 criteria is as follows: not more than one such result. The AL-2500 device had no false positives in this trial.

f. *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 as follows: no positive results. The AL-2500 device had no positive results. Other potential interferents were not evaluated with this device.

g. *Temperature:*

The DOT Model Specifications require testing 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 AL-2500 device had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC. At 40 C, the requirements are identical. At 40 C the AL-2500 device had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC.

h. *Vibration:*

The DOT Model Specifications require vibration testing to assess any possible vibrational effects. Twenty 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 AL-2500 device had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC.

i. *Assay Cutoff:*

For the purposes of performance testing, a BAC cutoff of 0.020 was used to distinguish positive from negative samples. The sponsor states that drivers may be impaired at a BAC of 0.05% and recommends they not operate a motor vehicle at or above this concentration.

*j. Method comparison with predicate device:*

The accuracy of this device is addressed in the precision section above. In addition, the sponsor conducted a consumer study comparing the AL-2500 to a professional breath alcohol device. The purpose of the study was to determine if consumers could correctly use and interpret the device using only the supplied User's Manual, and to compare the results to the professional device. There were 108 paired comparisons, and the volunteers ranged in age from 20 to 69 years of age. Each participant took their own breath alcohol reading with the AL-2500 and recorded the result. Immediately afterward, the participants were administered a breath alcohol test using an AlcoMate CA2000 operated by a trained individual. The breath alcohol concentrations ranged from a BAC of 0.00 to 0.31 (by the professional device). Linear regression analysis of the data shows a slope of 1.05, a y-intercept of 0.001, and a correlation coefficient of 0.96.

*j. Consumer use study:*

After the method comparison study, participants were asked questions about, the device labeling, device operation, correlation between device labeling instructions and operation, and interpretation of the display. Through survey questions, device labeling, device operation, correlation between device labeling instructions and operation, and interpretation of the display was found to be favorable as shown in the table below. StrAgr = Strongly Agree, SomAgr = Somewhat Agree, Nei = Neither Agree or Disagree, SomDis = Strongly Disagree, StrDis = Strongly Disagree.

Participant Information:

Gender	Number	Age Range	Number	Male	Female
M	67	20-29	43	26	17
F	41	30-39	21	16	5
Total:	108	40-49	20	7	13
		50-59	13	9	4
		60-69	4	3	1
		70-79	0		
		Other:	7	6	1
		Total:	108	67	41

Q1: "I understood how to use the AL2500 after reading the device labeling and instruction manual."

Q1	M	F	20-29	30-39	40-49	50-59	60-69	70-79	Other	Total
StrAgr	47	29	26	17	16	9	3		5	76
SomAgr	18	11	16	4	3	3	1		2	29
Nei	2		1		1					2
SomDis		1				1				1
StrDis										0
Total	67	41	43	21	20	13	4	0	7	108

Q2: "I was able to operate the AL2500 easily."

Q2	M	F	20-29	30-39	40-49	50-59	60-69	70-79	Other	Total
StrAgr	49	29	29	16	17	9	2		5	78
SomAgr	15	10	13	5	2	3	1		1	25
Nei	2	1	1		1		1			3
SomDis	1	1				1			1	2
StrDis										0
Total	67	41	43	21	20	13	4	0	7	108

Q3: "I was able to operate the AL2500 easily because of the instructions and labeling provided with the device."

Q3	M	F	20-29	30-39	40-49	50-59	60-69	70-79	Other	Total
StrAgr	49	26	28	15	16	9	2		5	75
SomAgr	13	13	14	3	3	3	2		1	26
Nei	5	1	1	3		1			1	6
SomDis		1			1					1
StrDis										0
Total	67	41	43	21	20	13	4	0	7	108

Q4: "I was able to easily understand and interpret the test results displayed by the AL2500."

Q4	M	F	20-29	30-39	40-49	50-59	60-69	70-79	Other	Total
StrAgr	53	29	35	15	16	9	2		5	82
SomAgr	12	10	8	5	2	4	2		1	22
Nei	2	1		1	1				1	3
SomDis		1			1					1
StrDis										0
Total	67	41	43	21	20	13	4	0	7	108

2. Other Supportive Instrument Performance Data Not Covered Above:

N/A

**K. Proposed Labeling**

Indicate whether the labeling is sufficient and it satisfies the requirements of 21 CFR section 809.10.

**L. Conclusion:**

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

