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

A. 510(k) Number:
k061922

B. Purpose for Submission:
New Device (This device has met the US Department of Transportation requirements for breath alcohol screening devices)

C. Measurand:
Breath Alcohol

D. Type of Test:
Quantitative (semiconductor oxide sensor)

E. Applicant:
Sentech Korea Corp.

F. Proprietary and Established Names:
AlcoScan AL-5000 Breath Alcohol Detector

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):
   Refer to indications for use below.

2. Indication(s) for use:
   The Alco-Scan AL-5000 Breath Alcohol Tester is intended to measure alcohol in human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.

3. Special conditions for use statement(s):
   Over-the-counter use

4. Special instrument requirements:
    Not applicable.

I. Device Description:

The device contains a semiconductor oxide sensor to detect the presence of alcohol. The display window displays the alcohol concentration or characters. The alcohol concentration is displayed in increments of 0.01% in the range 0.00% to 0.39% BAC. Characters are used to instruct the user and display the status of the device. The device also includes a beeper to give the user audible prompts.

To use the device, the power on/off button is depressed. The device will turn on and the display will show a countdown to indicate the warm-up. When ready for use the device will show a "READY" light. Users are instructed to exhale sharply and steadily into the mouthpiece for at least four seconds. The device will display WAIT again while it calculates the blood alcohol level. The display will then show the blood alcohol level; after 15 seconds, the device will turn off automatically.

Two replaceable 1.5V AA batteries power the device.

J. Substantial Equivalence Information:

1. Predicate device name(s):
    AlcoMate CA2000 Digital Alcohol Detector

2. Predicate 510(k) number(s):
    k041334

3. Comparison with predicate:

Similarities		
Item	Device	AlcoMate CA2000
Intended Use	Same	Measure alcohol in human breath.
Intended User	Same	General Public
Sensor Type	Same	Semiconductor-Oxide
Measurement Range	0.00 - 0.39 % BAC	0.00 - 0.40 % BAC
Display	Same	3 Digit
Construction	Same	Plastic Case with Internal Circuit Board
Differences		
Item	Device	AlcoMate CA2000
Blow Time	3-4 seconds	5 seconds
Power Source	2 1.5 V Batteries replaceable	Single 9 V Battery replaceable
Warm-up Time	less than 1 minute	below 20 Seconds
Dimensions	116x59x27 mm	120x59x27 mm
Weight	105 grams	200 grams
Mouthpiece	Disposable	Replaceable

K. Standard/Guidance Document Referenced (if applicable):
The sponsor states conformance to the following standards:

Department of Transportation National Highway Traffic Safety Administration [NHTSA 59 FR 39382] Highway Safety Programs; Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids

IEC 61326, Electrical equipment for measurement, control and laboratory use – EMC requirements

L. Test Principle:
The device contains a semiconductor oxide sensor to detect the presence of alcohol. In the absence of alcohol, while the heater is warming up, oxygen molecules in the air are chemisorbed on the surface of the particles, trapping the electrons in the semi conducting material. When it is exposed to an organic vapor such as ethanol, the chemisorbed oxygen is reduced and releases the trapped electrons. The flow of electrons causes a decrease of resistance, which is measured and converted to % BAC.

M. Performance Characteristics (if/when applicable):
1. <u>Analytical performance:</u>

   a. *Precision/Reproducibility:*
   The precision and accuracy of this device has been demonstrated through testing required by the US Department of Transportation in 59 FR 39382 (Alcohol Screening Devices). For precision and accuracy, these requirements (referred to as Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids) 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-5000 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 reports concentrations from 0.00% to 0.39%. However, DOT Model Specifications require accuracy testing at concentrations of 0.000, 0.008 and 0.032 BAC only; therefore true linearity was not evaluated. This device demonstrated acceptable performance according to the DOT Model Specifications as described above.

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 0.05% BAC & 0.10% BAC. This solution is used to calibrate the devices during manufacture.

d. *Detection limit:*
The DOT Model Specifications for screening devices 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. The AL-5000 device had no false positives in this trial.

e. *Analytical specificity:*
The DOT Model Specifications for screening devices require testing with cigarette smoke to assess any possible interference.
The manufacturer's labeling does not instruct the user to wait a specific time after consuming cigarettes before taking a reading, therefore the initial reading was taken within 1 minute as specified in the DOT model specifications. The subject was 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 positive results. The AL-5000 device had no positive results.

f. *Temperature:*
The DOT Model Specifications require testing at 10ºC and 40ºC to assess any possible effects of temperature.

At 10 ºC, 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-5000 device had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC.

At 40 ºC, the requirements are identical. Again the AL-5000 device had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC.

g. *Vibration*:
The DOT Model Specifications requires 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-5000 device had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC.

h. *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 in the labeling that consumption of alcohol in any amount may impair the ability to operate a motor vehicle.

2. Comparison studies:

a. *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 device to the predicate. 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 predicate device. The field test was performed involving 117 people, and the volunteers ranged in age from 20 to 60+ years of age. Each participant took their breath alcohol reading and recorded the result. Afterward, each participants were administered a breath alcohol test using the predicate device. The breath alcohol concentrations ranged from a BAC of 0.000 to 0.31. Linear regression of the data shows a slope of 0.997, y-intercept of 0 and a correlation coefficient of 0.98.

Also, the participants answered a questionnaire to determine how well they understood the user manual and how to use the device. The results are presented below:

	Strongly Agree	Somewhat Agree	Neither Agree nor Disagree	Somewhat Disagree	Strongly Disagree
I understood how to use the AL5000 after reading the device labeling and instruction manual	76	37	2	1	1
I was able to operate the AL-5000 easily	77	33	4	2	1
I was able to operate the AL-5000 easily because of the instructions and labeling provided with the device	73	36	4	3	1
I was able to easily understand and interpret the test results displayed by the AL-5000	76	36	3	2	0

A Flesch-Kincaid readability assessment for the labeling was performed. The Flesch-Kincaid reading ease is 57.1; the Flesch-Kincaid reading grade level is 7.9.

 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:
 Using these types of devices, alcohol is not 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.