

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE 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. Analyte:

Breath Alcohol

D. Type of Test:

Quantitative (Oxide Semiconductor Alcohol Sensor)

E. Applicant:

KHN Solutions, LLC

F. Proprietary and Established Names:

Blood Alcohol Detector (through relationship between breath and blood alcohol)
AlcoMate CA2000 Digital Alcohol Detector

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.3050
2. Classification:
Class I
3. Product Code:
DJZ
4. Panel:
Toxicology (91)

H. Intended Use:

1. Intended use(s):
Refer to Indications for use.
2. Indication(s) for use:
The AlcoMate CA2000™ Digital Alcohol Detector is intended to measure alcohol in human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.
3. Special condition for use statement(s):
Over-the-counter use

4. Special instrument Requirements:
NA

I. Device Description:

The AlcoMate CA2000 Digital Alcohol Detector is a self-contained unit with a breath pipe (for breath sampling) and a breath out opening at the top of the unit. The display window displays the alcohol concentration in increments of 0.01%. Below the display are a ready lamp, and battery low lamp, and an alcohol level warning lamp. If the alcohol concentration is greater than or equal to 0.05%, the red alcohol level warning lamp will light and the unit will beep. If the alcohol concentration is greater than or equal to 0.40%, the red alcohol level warning lamp will light, the unit will beep, and the display will read “Hot”. The unit can be powered by a single 9 volt battery or by using a DC power source plugged into the side. An on/off power switch on the front of the unit toggles the unit on and off.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Alco-Sensor III (Intoximeters Inc.)
2. Predicate K number(s):
Preamendment Device
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended User	Same	Professional Use DOT device
Power Source	9 V Battery or external DC power supply	9 V Battery
Battery Life	Same	300 Tests
Measuring Range	Same	0.00 – 0.40%
Construction	Same	Plastic case with internal circuit board
Size and weight	5” X 3¼”; 200 g	5” X 3½”; 171 g
Differences		
Item	Device	Predicate
Sensor Type	Semi-Conductor Oxide	Fuel Cell
Warmup Time	20 Seconds	None
Display	3 Digit LED	2 Digit LED

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

The sponsor states conformance to the following standards:

1. 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

2. IEC 60601-1, Safety of Medical Electrical Equipment, Part 1, General Requirements for Safety, including Amendment 1 and 2.
3. EN 55022:1988 Class B EMI Emissions
4. EN 50082-1:1997 EMC Immunity Standard

L. Test Principle:

The AlcoMate CA2000 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 an accurate deep lung sample, taking care not to block the breath out opening. A semiconductor oxide 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 can be quantitated and converted to % concentration of alcohol.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

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 AlcoMate 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%. 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.

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

This device uses an algorithm to convert deep lung breath alcohol concentration to blood alcohol concentration according to the relationship established by Henry's Law.

d. *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: not more than one such result. The AlcoMate device had no false positives in this trial.

e. *Analytical specificity:*

The DOT Model Specifications require testing with cigarette smoke 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 criteria for this trial is: no positive results. The AlcoMate device had no positive results.

Other potential interferents were not evaluated with this device.

f. *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 AlcoMate 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. Again the AlcoMate device had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC.

g. *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 AlcoMate 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 that drivers may be impaired at a BAC of 0.0 and recommends they not operate a motor vehicle at or above this concentration.

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 AlcoMate 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 127 paired comparisons, and the volunteers ranged in age from 21 to 87 years of age. Each participant took their own breath alcohol reading with the AlcoMate CA2000 and recorded the result. Immediately afterward, the participants were administered a breath alcohol test using a Lifeloc Model FC-10 operated by a trained individual. The breath alcohol concentrations ranged from a BAC of 0.00 to 0.38 (by the professional device). Linear regression analysis of the data shows a slope of 0.77, a y-intercept of 0.02, and a correlation coefficient of 0.94. After the study, participants were asked questions about ease of use and interpretation. The results are presented below:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
I found the device easy to use	0	0	1	48	63
I found the	0	0	4	48	60

instructions clearly written					
I understood the results	0	0	0	40	72

For the purposes of this study, the following were defined as acceptable interpretations of the BAC:

0.00 to 0.03	0.03 or 0.04	0.04 to 0.07	0.05 or above
Low	EITHER low or borderline	Borderline	I should not drive home

According to this scheme, all of the participants correctly interpreted their BAC.

b. Matrix comparison:

N/A. This device is intended for one sample matrix only.

3. Clinical studies:

a. Clinical sensitivity:

N/A

b. Clinical specificity:

N/A

c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:

N/A

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. Conclusion:

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