

K081855

DEC 19 2008

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY**

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

K081855

**B. Purpose for Submission:**

New device

**C. Measurement:**

Breath alcohol

**D. Type of Test:**

Quantitative (semiconductor gas sensor)

**E. Applicant:**

4376081 CANADA INC, AKA: IMPAIR AWARE

**F. Proprietary and Established Names:**

IA ALIS (Alcohol Level Indication system)

**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:

Refer to Indications for Use.

2. Indications for use:

The **IA ALIS** is a device intended to measure alcohol in human breath. Results given by this device are used in the detection of alcohol intoxication.

3. Special conditions for use statement:

Over the counter use

4. Special instrument requirements:

Not applicable.

## I. Device Description:

- The **IA ALIS** is a self-contained device that uses a semiconductor-based gas sensor and disposable straws for breath sampling and three 7-segment LED displays present the detected alcohol level.
- On the upper part of the screen there are fifteen lights for visual indication of the level of alcohol detected.
- The LED screen displays the user's blood alcohol equivalent concentration in two decimal places.
- On the bottom part of the screen there are four boxes for user instructions (step 1, step 2, step 3 and Wait).
- The device starts working when money is inserted into the machine. After the WAIT light goes on and the system performs a cleaning process, the BLOW light goes on and there is a beep when the device is ready to accept an air sample.
- As the user exhales with the straw into the hole, the device monitors the air pressure and blowing time. If the flow of the breath sample is sufficient, the indicator BLOW light goes from flashing to solid and the WAIT light goes on.
- Thereafter the system processes the air sample and gives a numerical result.

### Use instructions:

The machine waits for a coin or bill to be inserted and then measures the amount of alcohol on BAC and displays the results. The operation has two stages:

#### **Stage 1: Waiting for coin/bill**

The "Step 1" light flashes while the device is waiting for a coin/bill to be inserted. During this stage, the control card is monitoring the sensor's temperature using an on/off control circuit. The temperature is controlled between 34C and 38C as required by the alcohol sensor manufacturer.

## Stage 2: Money Insertion

As soon as a coin/bill is detected, the following process begin:

- The control card generates a beep indicating that a valid input for the coin/bill has been inserted.
- All LED's on the screen are turned off.
- The air pump is turned on for 5 seconds for cleaning and decontaminating the sensor and air conducts.
- The sensor heater is exposed to +5.5V.
- The system waits for the user to blow air into the device. They should take a straw to blow air into the machine. At the same time Step 3 light flashes (BLOW until WAIT light appears).
- After the sample has been collected the WAIT signal turns on.
- The system analyzes the sample for about 5 seconds.
- After the analysis is completed, the result is shown in the display;
- Meanwhile, the machine starts a cleaning process in which the alcohol sensor is decontaminated by increasing its voltage from 5V to 5.5V and the air pump is turned on for 20 seconds to clear the air conducts off any residues. If the result of the test was higher or equal to 0.12% BAC, the cleaning process is repeated twice. If the result was higher or equal to 0.20%, the cleaning process is repeated three times
- The control voltage returns to its nominal 5V value.

### Interpretation of results:

2. If the sample is less than 0.02% BAC no alcohol detected
3. If the sample is greater than 0.02%BAC alcohol detected

## J. Substantial Equivalence Information:

### 1. Predicate device name:

AlcoMateCA2000

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

k041334

### 3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Indication for use	Intended to measure alcohol in the human breath.	Intended to measure alcohol in the human breath. Measurements obtained by this device are used as an aid in the detection of alcohol intoxication.
Mode	Breath Alcohol Concentration	Breath Alcohol Concentration
Practitioner use	Over the counter	Over the counter
Type of sensor	Semi-conductor oxide Sensor	Semi-conductor oxide Sensor
Display	3 Digit LED	3 Digit LED

Measurement range	0.00-0.40%	0.00-0.40%
Anatomical site	Mouth	Mouth
<b>Differences</b>		
Blow time	8 Sec	3.5 Sec
Warm-up time	60 Sec	20 Sec
Power source	Switching Adapter 12V, 2A UL Listed	9 Volt Alkaline Battery
Mouthpiece	Disposable Straw	Replaceable
Battery life	N/A	300 tests
Construction	Printed circuit board inside a metallic case	Printed circuit board inside plastic case
Weight	17.6 Lb	120 grams

**K. Standard/Guidance Document referenced (if applicable):**

The sponsor states conformance to the following standards:

1. Department-of-Transportation-National-Highway-Traffic-Safety Administration [Docket No. NHTSA-2006-24964] Highway Safety Programs; Model Specifications for Devices to Measure Breath Alcohol.
2. EN 61000-6-2:2001 (IEC 61000-6-2:1999, modified) Part 6-2: Generic Standards Immunity for industrial environments.
3. EN 61000-6-3:2001 (IEC 61000-6-3:1996, modified) Part 6-3: Generic standards: Emission standard for residential, commercial and light-industrial environments.
4. CISPR 16-2-3: 2003 Specification for radio disturbance and immunity measuring apparatus and methods - Part 2-3: Methods c f measurement of disturbances and immunity - Radiated disturbance measurements.
5. EN 61000-3-2:2000 (IEC 61000-3-2: 2000 modified) Part 3-2: Limits for harmonic currents.
6. EN 61000-4-2:1995 +A1:1998 +A2:2001 (IEC 61000-4-2:1995 +A1:1998 +A2:2000) Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test.
7. EN 61000-4-11:1994 +A1:2001 (IEC 61000-4-11:1994 +A1:2000) Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity test

## L. Test Principle:

The sensing material in the type of gas sensor we use in the Impair Aware ALIS is metal oxide SnO<sub>2</sub>.

### *Explanation of how it works:*

When a metal oxide crystal SnO<sub>2</sub> is heated at high temperature in air, oxygen is adsorbed on the crystal surface with a negative charge. Then donor electrons in the crystal surface are transferred to the adsorbed oxygen, resulting in leaving positive charges in a space charge layer. Thus, surface potential is formed to serve as a potential barrier against electron flow. Inside the sensor, electric current flows through the conjunction parts (grain boundary) of SnO<sub>2</sub> micro crystals. At grain boundaries, adsorbed oxygen forms a potential barrier which prevents carriers from moving freely. The electrical resistance of the sensor is attributed to this potential barrier. In the presence of a deoxidizing gas, the surface density of the negatively charged oxygen decreases, so the barrier height in the grain boundary is reduced. The reduced barrier height decreases sensor resistance. The relationship between sensor resistance and the concentration of gas can be expressed by the following equation:

$$R_s = A[C]^{-a}$$

Where:  $R_s$  = electrical resistance of the sensor

$A$  = constant

$[C]$  = alcohol concentration

$a$  = slope of  $R_s$  curve

This resistance change can then be converted to a breath alcohol concentration which in turn is converted to a blood alcohol concentration.

## M. Performance Characteristics (if/when applicable):

### 1. Analytical performance:

#### *a. Precision/Reproducibility*

This device was not tested by the National Highway Traffic Safety Administration (NHTSA). The sponsor performed their own testing and collected performance data using the NHTSA requirements for precision and accuracy as a guide. These tests consist of 20 trials at a Blood Alcohol Concentration (BAC) of 0.008, 20 trials at a BAC of 0.032. Blood Alcohol Concentrations are simulated in breath by a Breath Alcohol Sample Simulator (BASS), "**MARK IIA SIMULATOR**", which provides an alcohol-in-air test sample with known alcohol level. The IA ALIS met all of the applicable NHTSA requirements for precision and accuracy.

Summary results were as follows:

<b>Concentration</b>	<b>0.008%</b>	<b>0.032%</b>
0.00% BAC	20	0
0.03% BAC	0	20

*b. Blank Reading*

The NHTSA requirements for the Blank Reading: These tests consist of 20 trials under normal laboratory conditions at 0.00% BAC with non-alcoholic human breath for breath devices and non alcoholic bodily fluids.

Summary results were as follows:

<b>Concentration</b>	<b>0.00%</b>
0.00% BAC	20

*c. Linearity/assay reportable range:*

This device will report concentrations from 0.00% to 0.40% BAC. However, the DOT Model Specifications require accuracy and precision testing up to a concentration of 0.03% BAC only; therefore, true linearity over the entire measuring range of the device was not evaluated. This device met all of the applicable NHTSA requirements for precision and accuracy as described above.

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

This device is traceable to a commercially available certified alcohol reference solution at a concentration of 0.10% BAC. This solution is used to calibrate the devices when manufactured.

The acceptance criterion for accuracy is  $\pm 10\%$  or  $\pm 0.01\%$  BAC

*e. Detection limit:*

The ALIS machine will report concentrations from 0.00% to 0.40% BAC.

*f. Analytical specificity: (Cigarette Smoke)*

The sponsor evaluated the possibility of cigarette smoke interference with the device. Five alcohol-free volunteers were asked to conduct five 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 **IA ALIS** Alcohol Tester produced no false positives results under these conditions.

*g. Temperature:*

40 devices were tested at 40°C, 20 trials at a concentration of 0.008% BAC, and 20 trials at 0.032% BAC. We also performed 20 trials at 10°C and 25°C.

Summary results were as follows:

Concentration	10°C	25°C	40°C
0.008% BAC	20/40	20/40	20/40
0.032% BAC	20/40	20/40	20/40

Note: The results are 20 trials / 40 devices

*h. Vibration:*

**IA ALIS** is a non-portable system, which is not subjected to any source of external or internal vibration. The system remains in a given site where users are moving towards it to take the test.

The **IA ALIS** was placed on a vibration table for 5 minutes and twenty samples were performed using a Breath Alcohol Sample Simulator. The results are presented in the table below:

Concentration	10- 30 Hz	30- 60 Hz
0.008	20/20	20/20
0.032	20/20	20/20

*f. Assay cut-off:*

For the purposes of performance testing, a BAC Cut-off of 0.02% was used to distinguish positive from negative samples.

All U.S. states have long-standing laws prohibiting driving while impaired by alcohol. In 49 states, it is also illegal to operate a motor vehicle with a blood alcohol concentration (BAC) above a specified limit. As of June 7, 2004 these states along with the District of Columbia and Puerto Rico, have adopted 0.08 % BAC as the legal level of intoxication.

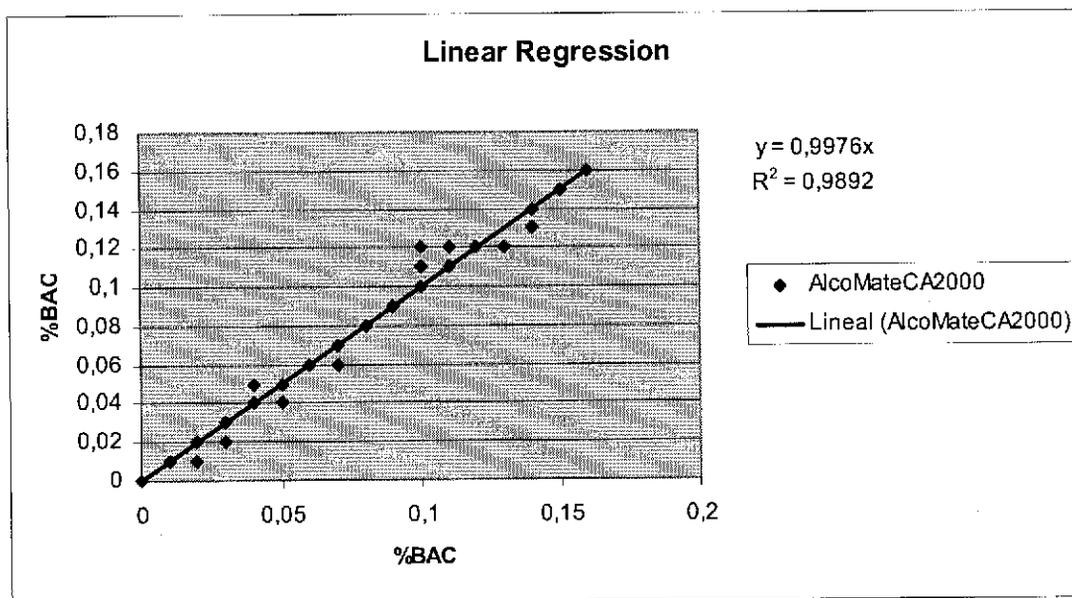
The sponsor states that drivers may be impaired at a BAC of 0.02% or more and recommends they do not operate a motor vehicle at or above this concentration.

2. Comparison studies:

*a. Method of comparison with predicate device:*

The sponsor performed a consumer study to determine if consumers could correctly use and interpret the device using only the supplied instructions on the front panel, and to compare the results to a device (**AlcoMateCA2000**). There were 65 paired comparisons, and the volunteers ranged in ages from 25 to 65

years (12 females and 53 males). Immediately afterward, the participants were administered a breath alcohol test using an **AlcoMateCA2000** operated by a trained individual. The breath alcohol concentrations ranged from 0.00%BAC to 0.16%BAC (by the **AlcoMateCA2000**). Linear regression analysis of the data yielded a slope of 0.9976, a y-intercept of 0 and a correlation coefficient of 0.9892. After the study, participants were asked questions about ease of use and interpretation.



Age Range	Number	Male	Female
21-29	5	3	2
30-39	35	28	7
40-49	10	9	1
50-59	12	10	2
60-69	3	3	0
<b>Total</b>	<b>65</b>	<b>53</b>	<b>12</b>

The results are presented below:

Questions:	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
The <b>IA ALIS</b> instructions are easy to understand.	0	0	0	10	55
I understood how to use the <b>IA ALIS</b> after reading the instruction manual	0	0	0	3	62
I was able to operate the <b>IA ALIS</b> easily.	0	0	0	5	60

I was able to understand and interpret the test results displayed by the IA ALIS.	0	0	0	6	59
I am interested in using this device	0	0	0	0	65

*b. Matrix comparison:*

Not applicable

3. Clinical studies:

*a. Clinical Sensitivity:*

Not applicable.

*b. Clinical specificity:*

Not applicable.

*c. Other clinical supportive data:*

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.

6. Software:

FDA has reviewed the applicant's Hazard Analysis and software development processes for this line of product types:

Yes  X  or No   (see annex 7,8,9)

7. Specimen Identification:

There is no mechanism to identify the specimen.

8. Specimen Sampling and Handling:

The user provides a breath sample by exhaling into the device. The instrument checks for adequate breath flow and volume during sampling.

9. Calibration:

The device is calibrated at the factory before is sent. The sponsor recommends a recalibration interval of three months (typical) or 300 uses. Whichever comes first.

The reasoning for the recalibration interval is because the bill capacity and the straw capacity are set at 300; for convenience we have set this value (300) as the estimated time frame to check on calibration. We consider that it's safer to set a calibration time so that our machines can always have excellent accuracy. See annexe 1 for more details.

10. Quality Control:

There are no external quality controls available for the consumer version of this device.

**0. Proposed Labeling:**

The labeling is sufficient and it satisfies the labeling requirements of 21 CFR 801.60, 21 CFR 801.61 and 21 CFR 801.62 for Over-the-Counter devices. **(See annexe 6)**

**R. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision. (see annex 6)



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Canada, Inc.  
c/o Federico Forero  
1100 Hammond Dr.  
Suite 410A-223  
Atlanta, GA 30328

**DEC 19 2008**

Re: k081855  
Trade Name: Impair Aware Alcohol Level Indication System (IA ALIS)  
Regulation Number: 21 CFR 862.3050  
Regulation Name: Breath-alcohol test system  
Regulatory Class: Class I (reserved)  
Product Codes: DJZ  
Dated: September 25, 2008  
Received: September 30, 2008

Dear Mr. Forero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

*Jean M. Cooper, M.S., D.V.M.*

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known): k081855

Device Name: Impair Aware Alcohol Level Indication System (IA ALIS)

Indication For Use:

The IA ALIS device is intended to measure alcohol in human breath. Measurements obtained by this device are used in the diagnostic of alcohol intoxication.

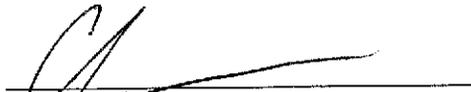
Prescription Use \_\_\_\_\_  
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use  X   
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

  
\_\_\_\_\_  
Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) k081855