510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:
k062545

B. Purpose for Submission:
New device

C. Measurand:
Breath alcohol

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

E. Applicant:
Resource Management International, LLC

F. Proprietary and Established Names:
RMI LCD 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):
   The device measures alcohol in human breath. Readings obtained by this device are used as an aid in the detection of alcohol intoxication.
2. Indication(s) for use:
   See Intended use.
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 shows the breath alcohol concentration in increments of 0.01% in the range 0.00% to 0.20% 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 beep twice and the LCD "BLOW" character appears, indicating the unit is ready for testing. Users are instructed to exhale slowly and consistently into the sensor slots at the

front of the unit for at three seconds and the test results will appear within 8 seconds. The BAC will appear on the LCD; after 30 seconds, the device will turn off automatically.

Two replaceable AAA 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	Predicate
Intended Use	Measure alcohol in human breath.	Same
Intended User	General Public	Same
Sensor Type	Semiconductor-Oxide	Same
Measurement Range	0.00 – 0.20 % BAC	0.00 - 0.40 % BAC
Display	3 Digit LED	Same
Construction	Plastic Case with Internal Circuit Board	Same
Differences		
Item	Device	Predicate
Blow Time	3 seconds	5 seconds
Power Source	2 AAA Batteries replaceable	Single 9 V Battery replaceable
Warm-up Time	5-15 seconds	15-60 Seconds
Dimensions	3.5” x 1.25”	5” x 2.55”
Weight	35 grams	120 grams
Mouthpiece	None Required	Replaceable

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

1. IEC 60601 –1, Safety of medical electrical equipment, Part 1, General requirements

for safety including amendment 1 and 2. (Device is battery operated, so requirements related to mains connection do not apply).

2. IEC 60601-2 , Electromagnetic compatibility (EMC) of medical devices

3. 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 LCD Alcohol Tester is designed to measure deep lung air to test for the presence of alcohol in the blood. The relationship between alcohol concentration in deep lung air and blood is established by Henry's Law in a ratio of 1:2100. The tin dioxide semiconductor gas sensor is sensitive to changes in conductivity due to the presence of alcohol in the breath. This change in conductivity due to the alcohol can be quantitated and converted to % concentration of alcohol.

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 semiconducting 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. Analytical performance:

a. Precision/Reproducibility:

The sponsor performed precision and accuracy testing in-house using blood alcohol concentration levels recommended by the National Highway Traffic Safety Administration. These requirements (referred to as DOT 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%. In addition, the sponsor conducted 20 trials at a BAC of 0.08%. 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. For the purposes of this study, a BAC of 0.020% is used to distinguish a positive from a negative result. The RMI device had no negatives at 0.08%, and 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 0.20%. 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 0.06% 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. The sponsor tested twenty "zero" concentration samples using non-alcoholic human breath. No false positives were produced using these samples.

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 RMI device had no positive results in this trial. Other potential interferents were not evaluated.

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. The RMI device had no positive results at 0.008 BAC and no non-positive results at 0.032% and 0.08% BAC. At 40 ºC, the RMI device had no positive results at 0.008% BAC and no non-positive results at 0.032% and 0.08% BAC.

Vibration*:*

The DOT Model Specifications requires vibration testing to assess any possible vibrational effects at 10 to 30 hertz and 30 to 60 hertz. Twenty trials are required at 0.008% BAC and 0.032% BAC. The RMI device had no positive results at 0.008% BAC and no non-positive results at 0.032% and 0.08% BAC.

f. Assay Cutoff

For the purposes of performance testing, a BAC cutoff of 0.20% 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 partially addressed in the precision section above. In addition, the sponsor conducted a consumer study comparing the device to an evidentiary 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 a comparator device. The field test was performed involving 40 people, and the volunteers ranged in age from 21 to 64 years of age. Each participant took their breath alcohol reading and recorded the result. Afterward, each participant were administered a breath alcohol test using the comparator device. The breath alcohol concentrations ranged from a BAC of 0.000 to 0.19%. Linear regression of the data shows a slope of 1.02267, y-intercept of -0.002 and a correlation coefficient of 0.91.

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

Survey Issue	Strongly Disagree	Disagree	Neither agree or disagree	Agree	Strongly Agree
I found the device easy to use	0	0	0	10	30
I understood the instructions and how to interpret the results	0	0	0	15	25

The participants were asked to interpret their result based on the instructions in the labeling below, and all of the participants correctly identified the range of concentrations listed in the labeling.

Less than 0.04% (driving skills may be impaired even at low levels)	0.04 to less than 0.08% (driving skills may be impaired at this level)	0.08% or greater (driving skills are always impaired at this level)

The sponsor assessed the reading level of the labeling by using the SMOG readability formula; the SMOG calculation indicated the labeling was at an 8th grade reading level.

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. Instrument Name:

RMI LCD Alcohol Tester

O. System Descriptions:

1. Modes of Operation:
User starts the test by pressing the on button. The device turns on and the display shows a countdown to indicate the warm-up. When ready for use the device beeps

twice and the LCD "BLOW" character appears indicating the unit is ready for testing. Users exhale slowly and consistently into the sensor slots at the front of the unit for at three seconds and the test results will appear within 8 seconds. The BAC appears on the LCD; after 30 seconds, the device automatically turns off.

2. Software:

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

   Yes X or No _____

3. Specimen Identification:

   There is no mechanism to identify the specimen

4. Specimen Sampling and Handling:

   The user obtains a breath sample by exhaling into the device.

5. Calibration:

   Factory calibrated

6. Quality Control:
   Typically, for theses types of devices, there are neither external quality control (QC) materials nor electronic QC functions.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Q. Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

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