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

A. 510(k) Number:
k043188

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

C. Measurand:
Breath Alcohol

D. Type of Test:
Quantitative (Semiconductor Oxide Alcohol Sensor)

E. Applicant:
Q3 Innovations, LLC

F. Proprietary and Established Names:
Alcohawk Precision ™ Digital Alcohol Detector
Blood Alcohol Detector (through relationship between breath and blood alcohol)

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 Alcohawk Precision ™ 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 conditions for use statement(s):
      Over-the-counter use
   4. Special instrument requirements:
      Not applicable.

I. Device Description:

The Alcohawk Precision ™ Digital Alcohol Detector is a self-contained unit with a mouthpiece port (for breath sampling) on the upper left hand side and an exhaust port opposite the mouthpiece. The mouthpieces are single use and should be replaced after each use. There is also an LED where the blood alcohol equivalent concentration is reported in per cent to three decimal places. The LED has a green light to indicate power and a yellow light to indicate that the unit is ready for use.

Immediately below the LED display, there is a single on/off button. On the back side of the unit is the battery compartment which houses a single 9 volt battery.

To use the unit, the power on/off button is depressed. A single beep will be heard and the green light will illuminate below the PWR sign in the display. The yellow light will also blink below the RDY sign in the display as the unit prepares for a measurement. The device is ready for use when the yellow light glows steadily and a single beep is heard. Users are instructed to inhale deeply and blow steadily into the mouthpiece for al least five seconds. Another beep sounds when the unit has sufficient sample to measure the alcohol in the breath. The user can then read the blood alcohol equivalent concentration in g/dL (commonly called "per cent") in the display.

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	Same	Over the Counter
Power Source	Same	Single 9 V Battery
Battery Life	100-300 Measurements	300 Measurements
Measurement Range	0.000 - 0.400 g/dL (%)	0.00 - 0.40 g/dL (%)
Accuracy	± 0.009 g/dL (%)	± 0.01 g/dL (%)
Sensor Type	Same	Semiconductor-Oxide
Blow Time	Same	5 seconds
Construction	Same	Plastic Case with Internal Circuit Board

Differences		
Item	Device	Predicate
Display	4 Digit LED	3 Digit LED
Warmup Time	15-60 Seconds	20 Seconds
Dimensions	4.25" x 2.75"	5" x 3.5"
Weight	130 grams	200 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 [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 55081-1: 1992 EMC - Generic emission standard - residential, commercial, light industry.
4. EN 50082-1: 1997 EMC - Generic immunity standard - residential, commercial, light industry.

L. Test Principle:
The Alcohawk Precision ™ 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 well established by Henry's Law in a ratio of 1:2100. The semiconductor oxide 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.

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 Alcohawk device had no negatives at 0.032 BAC, no positives at 0.008 BAC, and no positives at 0.000 BAC.
   b. *Linearity/assay reportable range:*
      This device will report concentrations from 0.000 to 0.400%. 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, Stability, Expected values (controls, calibrators, or methods):*
     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 criterion is: not more than one such result.
     The Alcohawk device had no false positives in this trial.

e.   *Analytical specificity:*
     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: no positive results. The Alcohawk device had no
     positive results.

     *The manufacturer's labeling instructs the user to wait 20 minutes after
     smoking, eating, or drinking before taking a reading.

     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
     Alcohawk 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 Alcohawk 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 Alcohawk 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 DOT performance testing, a BAC cutoff of 0.020 was used to distinguish positive from negative samples.

As of June 7, 2004, 49 states, along with the District of Columbia and Puerto Rico, have adopted .08 BAC as the legal level of intoxication in their state. Only Delaware remains at .10 BAC as the legally established level for drunk driving.

In their labeling, the sponsor states that driving skills *may* be impaired at a BAC of 0.04 - 0.06 and are *always* impaired at a BAC of 0.07 - 0.09.

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 AlcoHawk 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 85 paired comparisons, and the volunteers ranged in age from 21 to 70 years of age. Each participant took their breath alcohol reading with the AlcoHawk 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 0.000 to 0.136 (by the professional device). Linear regression analysis of the data shows a slope of 1.17, a y-intercept of 0.00, and a correlation coefficient of 0.940 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	2	36	47
I found the instructions clearly written	0	0	2	38	45
I understood the results	0	0	0	33	52

b. *Matrix comparison:*
　　　　　Not applicable. This device is intended for one sample matrix only.
　　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.