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

A. 510(k) Number:

k081855

B. Purpose for Submission:

New device for US consumer market

C. Manufacturer and Instrument Name:

Breath Alcohol

D. Type of Test or Tests Performed:

Quantitative (electrochemical fuel cell sensor)

E. System Descriptions:

1. Device Description:
   The Impair Aware Alcohol Level Indication System (IA ALIS) is a self-contained unit with semiconductor-based gas sensor and disposable straw for breath sampling, and a 3 digit LCD displays the alcohol level. On the upper part of the screen there are fifteen lights for visual level indication. The LCD screen displays the user's blood alcohol equivalent concentration to two decimal places. On the bottom part of the screen there are four boxes for user instructions (step1, step2, step3 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 a there is beep when the device is ready to accept an air sample. As the user exhales with the straw into the hole, the device monitors breath volume 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.

2. Principle of Operation:
   The sensing material in gas sensors is metal oxide (SnO_2). When the SnO_2 is heated at a certain 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_2 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 is expressed by an equation to determine the alcohol concentration.

3. Modes of Operation:
   This device has only one mode of operation. See section 2 above.

4. Specimen Identification:
   There is no mechanism to identify the specimen.

5. Specimen Sampling and Handling:
   The user provides a breath sample by exhaling into the device.

6. Calibration:
   The device is calibrated at the factory and sent directly to the end user. The sponsor recommends a recalibration interval of every 300 tests or every three months. These intervals are based on calibration stability data collected internally. The unit can be sent back to the factory for calibration or calibrated by the user following the calibration instructions in the user manual.

   Traceability

   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 during manufacture.

7. Quality Control:
   There are no external quality controls available for these types of devices for over-the-counter use.

8. Software:
   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes __X__   or No_____

F. Regulatory Information:

1. Regulation section:
   21 CFR § 862.3050

2. Classification:
   Class I, reserved

3   Product code:
    DJZ

4. Panel:
    Toxicology (91)

G. Intended Use:

1. Indication(s) for Use:

   This device is intended to measure alcohol in human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.

2. Special Conditions for Use Statement(s):

   For over the counter use

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   AlcoHAWK Precision Digital Alcohol Detector

   k043188

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Intended Use/Indications for Use	Same	Intended to measure alcohol in human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.
Measuring Range	Same	0.00 – 0.40 % BAC
Sensor type	Same	Semiconductor Oxide

Differences		
Item	Device	Predicate
Display	3 digit LCD	4 digit LCD
Warm-up Time	60 seconds	20 seconds
Blowing Time	8 seconds	5 seconds
Power Source	Switching Adapter 12V,	9 Volt Alkaline Battery

Differences		
Item	Device	Predicate
	2A UL Listed	
Weight	17.6 Lb	120 grams
Mouthpiece	Disposable Straw	Replaceable Mouthpiece

I. Special Control/Guidance Document Referenced (if applicable):

The sponsor claims conformance to the following standards:

a) Department of Transportation National Highway Traffic Safety Administration [Docket No. NHTSA-2006-24964] Highway Safety Programs; Model Specifications for Devices to Measure Breath Alcohol.

b) EN 61000-6-2:2001 (IEC 61000-6-2:1999, modified) Part 6-2: Generic Standards Immunity for industrial environments.

c) 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.

d) 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.

e) EN 61000-3-2:2000 (IEC 61000-3-2: 2000 modified) Part 3-2: Limits for harmonic currents.

f) 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.

g) 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 electrochemical fuel cell alcohol sensor in this device reacts with exhaled alcohol from the breath. As the alcohol gas passes through the cell, it initiates a chemical reaction resulting in a voltage change. This voltage change can then be converted to a breath alcohol concentration which in turn is converted to a blood alcohol concentration.

J. Performance Characteristics:

1. Analytical Performance:

    a. *Accuracy*:

    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 previously cleared device (AlcoMateCA2000). There were 65 paired comparisons, and the volunteers ranged in ages from 25 to 65 years (12 females and 53 males). Immediately after using the IA ALIS, 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.

Questions:

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

    This device was not eligible for testing 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 0.00, 20 trials at a BAC of 0.008, and 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.

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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 IA ALIS met all of the applicable NHTSA requirements for precision and accuracy.

c. *Linearity*:

This device will report concentrations from 0.00 to 0.400% BAC However, the DOT Model Specifications require accuracy and precision testing up to a concentration of 0.032% 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. *Carryover*:

Carryover studies are not required by NHTSA and were not performed using this device.

e. *Interfering Substances*:

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 IA ALIS device had no positive results.

*The manufacturer does not specify an exact wait time but for testing cigarette smoke interference, a wait time of one minute was used. The labeling indicates waiting 10 minutes after drinking or smoking before testing gives better results.

Other potential interferents were not evaluated with this device.

Temperature:
The DOT/NHTSA Model Specifications require testing at 10 and 40 ˚C to assess any possible effects of temperature.

At 10ºC, 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 Impair Aware Alcohol Level Indication System had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC.

At 40ºC, the requirements are identical. In this study the Impair Aware Alcohol Level Indication System had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC.

Vibration:
The DOT/NHTSA Model Specifications require vibration testing to assess any possible vibration related 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 Impair Aware Alcohol Level Indication System had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

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