

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

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

k080848

**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 AlcoHAWK PT-500 Digital Alcohol Detector is a self-contained unit with a disposable plastic mouthpiece for breath sampling. The mouthpiece is inserted into the BREATH PIPE IN opening on the left side of the device. Opposite the BREATH PIPE IN opening is the BREATH OUT opening. The display screen displays the user's blood alcohol equivalent concentration to three decimal places plus the temperature, text prompts and error messages. Below the display are the power button and enter and select buttons for menu navigation. Two AA batteries are inserted into a compartment on the back of the unit. The device is powered on by depressing the power button for approximately 1 second. The unit will beep and display "initializing" followed by "test" and "options" displayed simultaneously. To initiate a test, the user presses the enter button, after which the unit will display "Blow now". The unit beeps when the user starts blowing and beeps again when the breath sample has been obtained. The unit then displays "processing" followed by the BAC measurement approximately 3 seconds later.

2. Principle of Operation:

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.

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 200 tests or every six to twelve months if less than 200 tests have been performed. These intervals are based on calibration stability data collected internally. The unit must be sent back to the factory for calibration.

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	AlcoHAWK PT500	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.
Blowing Time	Same	5 seconds
Measuring Range	Same	0.00 – 0.40 % BAC
Mouthpiece	Same	Disposable, Replaceable
Display	Same	4 digit LCD
Weight	147 grams	130 grams
Intended User	Same	General Public (Over the Counter Use)

Differences		
Item	AlcoHAWK PT500	Predicate
Power Source	2 AA batteries	9 volt battery
Warm-up Time	10 seconds	15 – 60 seconds
Sensor type	Semiconductor Oxide	Electrochemical Fuel Cell

**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 [NHTSA Docket No. 94-004; Notice 2] Highway Safety Programs; Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids
- b. Electrical equipment for measurement, control and laboratory use EMC requirements - Part 1 : general requirements - Modified by NF EN 61326/A1:199810 (C46-050/A1),NF EN 61326/A2:200109 (C46-050/A2),NF EN 61326/A3:200405 (C46-050/A3)
- c. Electromagnetic compatibility (EMC). Part 4: testing and measurement techniques. Section 2: electrostatic discharge immunity test.
- d. Electromagnetic compatibility (EMC) - Part 4-3 : testing and measurement techniques - Radiated, radio-frequency, electromagnetic field 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:

This device has met the US Department of Transportation/ National Highway Traffic Safety Administration (NHTSA) requirements for breath alcohol screening devices.

a. *Accuracy:*

The sponsor performed a consumer study 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 professional device (the Lifeloc FC10 plus).

There were 99 paired comparisons, and the volunteers ranged in age from 22 to 65 years of age. Each participant took their breath alcohol reading with the Alcohawk PT-500 and recorded the result. Immediately afterward, the participants were administered a breath alcohol test using the Lifeloc FC10 plus operated by a trained individual. The breath alcohol concentrations ranged from BAC of 0.000 % to 0.127 % (by the Lifeloc FC10). Linear regression analysis of the data showed a slope of 0.9221, a y-intercept of 0 and a correlation coefficient of 0.9647. After the study, participants were asked questions about ease of use and interpretation. The results are presented below:

<b>Participant Information</b>	
<b>Gender</b>	<b>#</b>
<b>M</b>	<b>59</b>
<b>F</b>	<b>39</b>
<b>Total</b>	<b>98*</b>

\* One participant who provided a breath sample was unable to complete the questionnaire.

**Questions:**

	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neither Agree or Disagree</b>	<b>Agree</b>	<b>Strongly Agree</b>
I found the device easy to use	0	0	4	25	69
I understood how to use the device after reading the instructions	0	0	0	21	77
I was able to easily understand and interpret the test results displayed by the device.	0	0	0	13	85

*b. 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 PT-500 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 only; therefore, true linearity over the entire measuring range of the device was not evaluated by DOT. 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 Alcohawk PT-500 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 interferences were not evaluated with this device.

2. Other Supportive Instrument Performance Data Not Covered Above:

**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.