

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

A. 510(k) Number:

k091714

B. Purpose for Submission:

New devices

C. Manufacturer and Instrument Name:

Skyfine Incorporated Alcodigital Breathalyzer Models AT576, AT577, AT578, and AT579

D. Type of Test or Tests Performed:

Quantitative (electrochemical fuel cell sensor)

E. System Descriptions:

1. Device Description:

The AT576, AT577, AT578, and AT579 models are self-contained units with a mouthpiece at the top of the device for breath sampling. The AT576 has SET, TEST, and PRINT buttons. Models AT577, AT578, and AT579 have TEST and MEMORY buttons. All models have an LCD display that shows the breath alcohol concentration (BAC) to three decimal places.

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 500 tests or every twelve months. These intervals are based on calibration stability data collected internally. The unit must be sent back to the factory for calibration.

Traceability:

These devices are traceable to a commercially available certified ethyl alcohol reference solution.

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 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 and 510(k) number:

AlcoHAWK PT500 Digital Alcohol Detector

k080848

2. Comparison with Predicate Device:

Similarities		
Item	Model AT576	AlcoHAWK PT500
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.
Sensor type	Same	Electrochemical Fuel Cell
Blowing Time	6 seconds	5 seconds
Mouthpiece	Same	Disposable, Replaceable
Display	Same	4 digit LCD
Intended User	Same	OTC

Similarities		
Item	Models AT577, AT578, AT579	AlcoHAWK PT500
Intended Use/Indications for Use	Same	Intended to measure alcohol in human breath. Measurements obtained by these devices are used in the diagnosis of alcohol intoxication.
Sensor type	Same	Electrochemical Fuel Cell
Blowing Time	6 seconds	5 seconds
Mouthpiece	Same	Disposable, Replaceable
Display	Same	4 digit LCD
Intended User	Same	OTC

Differences		
Item	Model AT576	AlcoHAWK PT500
Power Source	1 Nine volt battery	2 AA batteries
Warm-up Time	15 seconds	10 seconds
Measuring Range	0.000 – 0.300 %	0.000 – 0.400 %
Weight	110 g	147 g

Differences		
Item	Models AT577, AT578, AT579	AlcoHAWK PT500
Power Source	1 Nine volt battery	2 AA batteries
Warm-up Time	15 seconds	10 seconds
Measuring Range	0.000 – 0.200 %	0.000 – 0.400 %
Weight	100 g	147 g

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. EN 61000-6-1:2007; compatibility (EMC) – part 6-1: Immunity for residential, commercial, and light-industrial environments
- c. EN 61000-6-3:2007; Electromagnetic compatibility (EMC). Emission standards for residential, commercial, and light-industrial environments

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:

All four models have met the US Department of Transportation/ National Highway Traffic Safety Administration (NHT SA) requirements for breath alcohol screening devices.

a. *Accuracy:*

The sponsor performed a consumer study using model AT579 to determine if consumers could correctly use and interpret the device using only the operation manual, and to compare the results to the predicate device. There were 40 paired comparisons, and the volunteers ranged in age from 21 to 69 years of age. Each participant took their breath alcohol reading with the model AT579 and recorded the result. Immediately afterward, the participants were administered a breath alcohol test using the predicate device operated by a trained individual. The breath alcohol concentrations ranged from BAC of 0.000 % to 0.092 % (by the predicate). Linear regression analysis of the data showed a slope of 1.0298, a y-intercept of 0.0018 and a correlation coefficient of 0.9989. After the study, participants were asked questions about ease of use and interpretation. Participant demographics and responses to the survey are presented below:

Participant Information	
Gender	#
M	23
F	17
Total	40

Questions:

Question	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
I found the device easy to use	0	0	0	15	25
I understood how to use the device after reading instruction manual	0	0	1	13	26
I was able to easily understand and interpret the test results displayed by the device	0	0	0	8	32

b. Precision/Reproducibility:

This device was not tested by the National Highway Traffic Safety Administration (NHTSA). Instead, the sponsor performed their own testing on all four models (AT576, AT577, AT578, and AT579) and collected performance data using the NHTSA requirements for precision and accuracy as a guide. 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 four Alcodigital models met all of the applicable NHTSA requirements for precision and accuracy.

c. *Linearity:*

This device will report concentrations from 0.00 to 0.200% BAC for the AT577, AT578, and AT579 models and from 0.00 to 0.300% BAC for the AT576 model. 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. These devices 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 these devices.

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 four Alcodigital models had no positive results.

Other potential interferents were not evaluated with this device.

2. Other Supportive Instrument Performance Data Not Covered Above:

a. *Limit of Detection*

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 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. These devices had no false positives in this trial.

b. 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 devices 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 devices had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC.

c. 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. These devices had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC.

d. Cutoff

For the purposes of performance testing, a BAC cutoff of 0.020 was used to distinguish positive from negative samples.

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.