

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

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

k123470

**B. Purpose for Submission:**

New devices

**C. Manufacturer and Instrument Names:**

PAS Systems International Inc.

PAS Alcovisor Satellite Breath Alcohol Analyzer

PAS Alcovisor Mars Breath Alcohol Analyzer

**D. Type of Test or Tests Performed:**

Breath Alcohol

**E. System Descriptions:**

1. Device Description:

PAS Alcovisor Satellite Breath Alcohol Analyzer. The front of this device consists of an indicator lamp, display screen, on/off button, and settings button. The bottom of the device consists of a reset button, a USB “in” port, and a USB “out” port. The USB connectivity is for charging purposes only. No data is passed to or from the Satellite device. A small flashlight is included in the top of the device. A disposable mouthpiece can be fitted to an opening on either side of the device. The blood alcohol equivalent concentration (BAC) is reported in percent to three decimal places on the display. Users are instructed to power on the device by depressing the on/off button for 2 – 3 seconds, after which the display will read “Blow”, indicating that it is ready for a measurement to be taken. Users are then instructed to insert a new mouthpiece and to blow evenly into the mouthpiece for 3 – 5 seconds. The device will beep during the measurement and users are instructed to stop blowing when the device stops beeping. Results are displayed a few seconds later.

PAS Alcovisor Mars Breath Alcohol Analyzer. The front of this device consists of the display screen only. A mouthpiece port for the disposable mouthpieces and the on/off button are located on the side, and a removable battery cover is located on the back. The blood alcohol equivalent concentration (BAC) is reported in percent to three decimal

places on the display. Users are instructed to power on the device by depressing the on/off button for 2 – 3 seconds, and to insert a new mouthpiece. The display will read “Blow” with a moving zero, indicating that it is ready for a measurement to be taken. Users are then instructed to breathe in deeply and to blow evenly into the mouthpiece for 3 – 5 seconds. The device will beep during the measurement and users are instructed to stop blowing when the device stops beeping. Results are displayed a few seconds later.

## 2. Principles of Operation:

The PAS Alcovisor Satellite and the PAS Alcovisor Mars are breath alcohol analyzers designed to sample a user’s deep lung breath to test for the presence of alcohol. The sensor is an electrochemical fuel cell which will only respond to alcohol. After the user blows into the device using a disposable mouthpiece a small sample of breath is drawn into the fuel cell by an automatic pump and a chemical reaction occurs between the alcohol and fuel cell. This reaction generates an electrical current which is directly related to the amount of alcohol in the sample. The current is then converted to a Blood Alcohol Concentration (BAC) level and displayed for the user. The relationship between alcohol in a person’s deep lung breath and in their blood is well established using Henry’s law, which gives a ratio of 2100:1. The Satellite and Mars are handheld devices made from durable plastic with an internal circuit board. The Satellite uses an internal rechargeable battery and the Mars uses three AAA batteries.

## 3. Modes of Operation:

Both devices have an automatic and manual sampling mode. The manual sampling mode is designed for persons with reduced lung capacity who may not be able to activate the automatic sampling mode. The labeling instructs users that when using the manual mode they should blow into the device for a minimum of 6 seconds, and that failure to do so may result in an inaccurate reading.

## 4. Specimen Identification:

There is no mechanism to identify the specimen; however, the Satellite Alcovisor device can recall the last 10 tests taken. The Alcovisor Mars can recall only the last measurement taken.

## 5. Specimen Sampling and Handling:

The user provides a breath sample by blowing 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 250 tests or every 12 months, whichever comes first. These intervals are based on calibration stability data collected internally. The unit must be sent back to the factory for calibration.

Traceability:

Each device is calibrated to a 0.100% certified wet bath simulator solution which is traceable by lot number associated with a certificate of analysis from the manufacturer of the 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       No

**F. Regulatory Information:**

1. Regulation section:

21 CFR § 862.3050, Breath-alcohol test system

2. Classification:

Class I, reserved

3. Product code:

DJZ

4. Panel:

Toxicology (91)

**G. Intended Use:**

1. Indication(s) for Use:

PAS Alcovisor Satellite Breath Alcohol Analyzer

The PAS Alcovisor Satellite Breath Alcohol Analyzer is intended to measure alcohol in human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.

PAS Alcovisor Mars Breath Alcohol Analyzer

The PAS Alcovisor Mars Breath Alcohol Analyzer 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 (OTC) use

**H. Substantial Equivalence Information:**

1. Predicate Device Name and 510(k) number:

AlcoHAWK PT-500 Digital Alcohol Detector (k080848)

2. Comparison with Predicate Device:

<b>Similarities</b>		
<b>Item</b>	<b>Candidate Device (Alcovisor Satellite)</b>	<b>Predicate: AlcoHAWK PT-500 Digital Alcohol Detector (k080848)</b>
Intended 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
Mouthpiece	Same	Single Use Disposable
Intended User	Same	General Public (Over the Counter Use)
Measuring Range	Same	0.00 – 0.40 % BAC
Blowing Time	3 – 5 seconds	5 seconds
Display	Same	4 digit LCD
<b>Differences</b>		
<b>Item</b>	<b>Candidate Device (Alcovisor Satellite)</b>	<b>Predicate: AlcoHAWK PT-500 Digital Alcohol Detector (k080848)</b>
Power Source	Internal Rechargeable Battery	2 AA batteries
Warmup Time	5 seconds	10 seconds
Weight	4.2 oz	5.2 oz with batteries

<b>Similarities</b>		
<b>Item</b>	<b>Candidate Device (Alcovisor Mars)</b>	<b>Predicate: AlcoHAWK PT-500 Digital Alcohol Detector (k080848)</b>
Intended 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
Mouthpiece	Same	Single Use Disposable
Intended User	Same	General Public (Over the Counter Use)
Measuring Range	Same	0.00 – 0.40 % BAC
Blowing Time	3 – 5 seconds	5 seconds
Display	Same	4 digit LCD
<b>Differences</b>		
<b>Item</b>	<b>Candidate Device (Alcovisor Mars)</b>	<b>Predicate: AlcoHAWK PT-500 Digital Alcohol Detector (k080848)</b>
Power Source	3 AA Batteries	2 AA Batteries
Warmup Time	5 seconds	10 seconds
Weight	4.0 oz with batteries	5.2 oz with batteries

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

- EN 61000-3-2 Electromagnetic Compatibility (EMC) Part 3-2: Limits for harmonic current emissions
- EN 61000-3-2+A1+A2: Limits for harmonic current emissions (equipment input current up to and including 16A per phase)
- EN 61000.6-1: Immunity for residential, commercial and light-industrial environments
- EN 61000-6-3: Emission Standard for residential, commercial and light-industrial environments
- EN 61000-3-3: Electromagnetic Compatibility (EMC) Part 3-3: Limitation for voltage supply for equipment with rate current <16A
- Conformance Testing of Screening Devices to Measure Alcohol in Bodily Fluids (NHTSA/U.S.DOT)

**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 for use. Results were compared to an evidential breath alcohol tester (the Alcovisor Mercury).

Satellite

Twenty-eight participants took their breath alcohol reading with the candidate device and recorded the result. Immediately afterward, the participants were administered a breath alcohol test using the evidential device. The breath alcohol concentrations ranged from BAC of 0.000 to 0.045 by the evidential device. Linear regression analysis of the data showed a slope of 0.9638, a y-intercept of 0.0007 and a correlation coefficient of 0.9680. After the study, participants were asked to respond to statements about ease of use and interpretation of the device. Results are summarized as follows:

<b>Question</b>	<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	0	4	24
I found the Owner's Manual to be clearly written	0	0	0	5	23
I was able to understand the test results displayed by the device	0	0	0	1	27

## Mars

Twenty-eight participants took their breath alcohol reading with the candidate device and recorded the result. Immediately afterward, the participants were administered a breath alcohol test using the evidential device. The breath alcohol concentrations ranged from BAC of 0.000 to 0.047 by the evidential device. Linear regression analysis of the data showed a slope of 0.9981, a y-intercept of 0.0018 and a correlation coefficient of 0.9083. After the study, participants were asked to respond to statements about ease of use and interpretation of the device. Results are summarized as follows:

<b>Question</b>	<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	0	4	24
I found the Owner's Manual to be clearly written	0	0	0	5	23
I was able to understand the test results displayed by the device	0	0	0	1	27

### *b. Precision/Reproducibility:*

The precision and accuracy of the Satellite and Mars devices has previously been demonstrated through testing at the US Department of Transportation (DOT). 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 Satellite and Mars devices met all of the applicable NHTSA requirements for precision and accuracy.

c. *Linearity:*

The Satellite and Mars devices will report concentrations from 0.000 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. Both 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 Satellite and Mars devices had no positive results.

\*The sponsor's labeling recommends the user wait 15 minutes after consuming alcohol, smoking, or eating to test a breath sample.

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. The Satellite and Mars 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 PAD – Personal Alcohol Detector had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC. At 40° C, the requirements are identical. The Satellite and Mars 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. The Satellite and Mars 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.