

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

A. 510(k) Number:

k090766

B. Purpose for Submission:

New Device

C. Manufacturer and Instrument Name:

Lifeloc Technologies, Inc. LifeGuard

Lifeloc Technologies, Inc. BacTrack B90

D. Type of Test or Tests Performed:

Quantitative (electrochemical fuel cell sensor)

E. System Description:

1. Device Description:

The LifeGuard and BacTrack B90 models are self-contained units with a mouthpiece at the top of the device for breath sampling. A round power button and a triangular execute button are located on the front of the unit along with the display screen. The power button turns the unit on and performs a self-test. If the self-test passes, READY is displayed on the display. The unit is powered by a single nine volt battery. The device also includes disposable mouthpieces. The display window shows the breath alcohol concentration in increments of 0.001% from 0.000% to 0.400% BAC. A graphical display and audible prompts assist the user in providing an appropriate breath sample.

2. Principle of Operation:

The LifeGuard and BacTrack B90 are alcohol screening devices used for the detection of alcohol in the breath. The devices employ a fuel cell sensor. An alcohol fuel cell uses an alcohol oxidation reaction. In an alcohol oxidation reaction, a fixed number of electrons are freed per molecule of alcohol. If alcohol is present, a corresponding voltage is generated from the fuel cell, which is proportional to the alcohol content of the breath sample.

3. Modes of Operation:

These devices have only one mode of operation.

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:

In their labeling, the sponsor recommends that the devices be recalibrated at least once every 12 months. The device must be returned to the manufacturer 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 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:

The LifeGuard and BacTrack B90 devices are intended to measure alcohol in human breath. Measurements obtained from these devices are used in the diagnosis of alcohol intoxication.

The LifeGuard and BacTrack B90 devices are intended to be used by the general adult population and by qualified personnel, such as physicians, nurses, and technicians.

The LifeGuard and BacTrack B90 devices are intended to be used by adults (age 21 and over) in measuring alcohol intoxication in themselves or others.

2. Special Conditions for Use Statement(s):

Intended to be used in both home (over-the-counter) and clinical settings.

H. Substantial Equivalence Information:

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

Drager Alcotest 6510, cleared under k063443

AlcoHawk PT-500, cleared under k080848

2. Comparison with Predicate Device:

Similarities			
Item	New Device	Drager AlcoTest 6510	AlcoHawk PT-500
Intended Use	Intended to measure alcohol in human breath. Measurements obtained from this device are used in the diagnosis of alcohol intoxication.	Same	Same

Similarities			
Item	New Device	Drager AlcoTest 6510	AlcoHawk PT-500
Sensor Type	Electrochemical Fuel Cell	Same	Same
Mouthpiece	Single use disposable	Same	Same

Differences			
Item	New Device	Drager AlcoTest 6510	AlcoHawk PT-500
Intended population	Over the counter and in clinical settings	Over the counter	Over the counter
Power source	9 volt battery	2 AA batteries or rechargeable NiMH battery	2 AA batteries
Measuring range	0.000 – 0.400% BAC	0.000 – 0.500% BAC	0.000 – 0.400% BAC
Battery life	300 tests	1500 tests	200 tests
Warmup time	None	None	10 – 20 seconds

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

1. Department of Transportation; National Highway Traffic Safety Administration; Highway Safety Programs; Model Specifications for Devices to Measure Breath Alcohol
2. EN 55011: 2007 Industrial, Scientific, and Medical Radiofrequency Equipment. Electromagnetic disturbance characteristics. Limits and methods of measurement.
3. EN 61000-4-2:1995 +A1:1998 +A2:2001 Testing and measurement techniques Electrostatic Discharge.
4. IEC 61000-4-3:2006 Electromagnetic Compatibility (EMC) Part 4-3, Radiated RF Immunity.
5. IEC 61000-4-6:2006 Electromagnetic Compatibility (EMC) Part 4-6, Conducted RF Immunity.
6. IEC 61000-4-8:2001 Electromagnetic Compatibility (EMC) Part 4-8, Power Frequency H-Field Immunity.
7. IEC 60601-1:1988, 1991, 1995 Standard for Safety for Medical Electrical Equipment, Part 1: General Requirements for Safety.

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 LifeLoc FC10). Twenty-eight participants took their breath alcohol reading with the new device and recorded the result. Immediately afterward, the participants were administered a breath alcohol test using the professional device. The breath alcohol concentrations ranged from BAC of 0.000 to 0.116 by the evidential device. Linear regression analysis of the data showed a slope of 0.889, a y-intercept of 0.006 and a correlation coefficient of 0.965.

After the study, participants were asked questions about the ease of use, instructions and about the ability to understand and interpret the test results displayed by the device. The results are presented below:

Question	Strongly Disagree	Disagree	Neither Agree Or Disagree	Agree	Strongly Agree
I found the device easy to use	0	0	0	4	24
I found the operations manual to be clearly written	0	0	0	8	20
I was able to understand the test results displayed by the device	1*	0	0	4	23

* One volunteer had not consumed alcohol but believed he had done so when he drank a non-alcoholic mixer. When he obtained a result of zero he felt that he did not understand the result. The reading of zero was confirmed by the evidential device.

b. *Precision/Reproducibility:*

This device was not tested 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 requirements (referred to as Model Specifications) consist of 20 trials at a Blood Alcohol Concentration (BAC) of 0.000, 20 trials at a BAC of

0.008 and 20 trials at a BAC of 0.032. BACs 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. The device had no negatives at 0.032 BAC, no positives at 0.008 BAC and no positives at 0.000 BAC. Negatives are defined as being less than 0.020 BAC. Positives are defined as being greater than or equal to 0.020 BAC.

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. 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 sponsor chose to duplicate the NHTSA requirements for cigarette smoke interference. The sponsor evaluated the possibility of cigarette smoke interference with the device. An alcohol-free person who smokes cigarettes smoked approximately one half of a cigarette. Within one minute after smoking, the subject took a breath alcohol reading. The subject then repeated this procedure for 5 trials. The acceptance criterion for this trial is: no positive results. The device produced all negative results in this study.

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 device 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 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 device 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 device 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.