

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

A. 510(k) Number:

k082086

B. Purpose for Submission:

New device for US consumer market

C. Manufacturer and Instrument Name:

The Ashley Collection Protocol Alcohol Breath Checker

D. Type of Test or Tests Performed:

Quantitative (Semiconductor Oxide Alcohol Sensor)

E. System Descriptions:

1. Device Description:

The Protocol Breath Alcohol Tester is a self-contained unit with a sensor at the top of the unit for breath sampling. The LCD display displays a timer that can be used as a count-up timer or a count down timer. There are three buttons corresponding to min, hour and start. The device also has three LCD colors – green, yellow or red that correspond to the BAC concentration levels. Two AAA batteries are inserted into the back of the unit. The device is powered on by depressing the power button until the green LCD light is lit. To initiate a test, the user presses the power button and holds it continuously during the testing. The user blows for three seconds slowly and consistently and the LED codes will appear based on the breath alcohol concentrations. A flashlight is also incorporated into the device.

2. Principles of Operation:

The Protocol Alcohol Breath Checker is designed to measure deep lung air to test for the presence of alcohol in the blood. The tin dioxide semiconductor gas sensor is sensitive to changes in conductivity due to the presence of alcohol in the breath. This change in conductivity due to the alcohol can be quantitated and converted to % concentration of alcohol.

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 cannot be recalibrated after it has been used. The labeling states that the device should be discarded after one year of use.

Traceability:

This device is traceable to a commercially available certified alcohol reference solution at a concentration of 0.06% 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

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:

Connectables Pocket Breathalyzer

k052448

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Indications for use	The device is intended to measure alcohol in human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.	Same
Analysis Mode	Breath Alcohol Concentration	Same
User	Home use	Same
Blowing time	3 seconds	Same
Display	Three colored LEDs: red, yellow and green	Same
Power Source	2 AAA batteries	Same
Measurement Range	0.00- 0.40% BAC	Same
Type of sensor	Semiconductor-Oxide Sensor	Same

Similarities		
Item	Device	Predicate
Flashlight	Yes	Yes

Differences		
Item	Device	Predicate
Display interpretation	Red: BAC>0.08 Yellow: BAS 0.04 to 0.08 Green: BAC <0.04	Red and yellow: BAC 0.08 or more Yellow: BAC 0.05 to 0.08 Green: BAC <0.05
Battery life	300 tests	400 tests
Size	1.5" x 3"	2.64" x 2.1"
Weight	51 grams	42 grams
Timer	Count up or count down	Timer not incorporated

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

The sponsor claims conformance to the following standards:

- 1) EN 61000-6-3: 2001 & EN 61000-6-1:2001; Electromagnetic compatibility (EMC). Generic standards. Emission standard for residential, commercial and light-industrial environments
- 2) EN 55022:1998 & EN 55024:1998 (EN 6100-4-2/-3) Measuring radiated emissions

J. Performance Characteristics:

Semi-quantitative devices such as the Protocol Alcohol Breath Checker device are not eligible for testing by the National Highway Traffic Safety Administration (NHTSA). In lieu of NHTSA testing, the sponsor collected performance data to support a claim of substantial equivalence for the device. This included testing at BAC concentrations of zero, 0.025%, 0.065%, and 0.10% in addition to an accuracy study performed by consumers.

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 and compare to the results obtained by a commercially available NHTSA approved professional breath alcohol tester (the LifeLoc FC10 plus). There were 53 paired comparisons, and the volunteers ranged in age from 21 to 65 years of age. Each participant took their breath alcohol reading with the Protocol Alcohol Breath Checker 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 0.00 to 0.385% (by the LifeLoc FC10 device).

	Protocol Alcohol Breath Checker color		
	Green corresponding to 0.0 to 0.049 BAC	Yellow (0.05 to 0.079)	Red (0.08 and above)
LifeLoc concentrations between 0.0 to 0.049	16 of the 18 samples were green	2 of the 18 samples were yellow	
LifeLoc concentrations between 0.05 to 0.079		23 of the 23 samples were yellow	
LifeLoc concentrations above 0.08			12 of the 12 samples were red.

Two of the fifty-three readings were for % BAC of 0.047 and 0.049 were yellow. The sponsor determined that these two samples were close to the 0.050 %BAC green/yellow threshold. The numbers in the chart above represent a 96% agreement to the professional device.

The sponsor had the study participants complete a questionnaire to determine if the user understands the device and what the results mean. The participants were asked the following questions and the responses are shown in the table below. The package insert received a Flesch-Kincaid readability score of 7.5.

How long should you wait after drinking to use the tester?	98.1% of participants answered correctly.				
How long should you wait between tests?	98.1% of participants answered correctly.				
What does it mean if only the green LED lights up?	96.2% of participants answered correctly.				
What does it mean if the only the yellow LED lights up?	98.1% of participants answered correctly.				
What does it mean if the yellow and red LEDs light up?	98.1% of participants answered correctly.				
What does it mean if none of the LEDs light up?	100% of participants answered correctly.				
How long should you blow into the sensor?	100% of participants answered correctly.				
How long should you press the top button to warm up the sensor?	98.1% of participants answered correctly.				
Question	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
I found the device easy to use	1	0	2	15	35
I understood the instructions and how to interpret the results.	0	0	3	24	26
Interpreting the results*:	Less than 0.05% (driving skills may be impaired even at low levels),		0.05 to 0.08% (driving skills may be impaired at this level)	0.08% or greater (driving skills are always impaired at this level).	
My result indicates that my Blood Alcohol Level is (Check ONE box at right)	100% of participants answered correctly.				
How long should you wait after drinking to use the tester?	98.1% of participants answered correctly.				

*The labeling states “CAUTION: Your driving may be impaired at ANY level of alcohol consumption. This may be true even if only the green light is lit. DON’T DRINK AND DRIVE!”

The sponsor also conducted a stability study to support a claim that the device can provide accurate results after 375 tests (without calibration). Over 10 successive days, the device was tested at 0.10% BAC, then tested 30 second later at 0.00 %BAC. This was repeated for 375 times over 10 days with no deviations from the expected results. The study result supports the claim that the device was capable of providing results for 375 uses.

b. Precision/Reproducibility:

The sponsor performed precision and accuracy testing for three BACs using a Breath Alcohol Sample Simulator (BASS), which provides an alcohol-in-air test sample with known alcohol concentrations, flow rate, and air

composition. The sponsor performed 20 tests at 0.025% BAC, 20 at 0.065% BAC, and 20 at 0.10% BAC. Study results are summarized in the table below.

Concentration (center of range)	Green (less than 0.05%)	Yellow (0.05% to 0.08%)	Red (greater than 0.08%)
0.025 BAC	20	0	0
0.065 BAC	0	20	0
0.10 BAC	0	0	20

The NHTSA protocol requires testing of zero concentration samples to assess the possibility of false positives. As part of their stability study, the sponsor analyzed 375 zero concentration samples over 10 days. No false positives were observed.

c. Linearity:

Since this device reports a range and not an actual concentration, it is not possible to evaluate linearity.

d. Carryover:

Carryover studies were not performed using this device.

e. Interfering Substances:

This sponsor chose to duplicate the NHTSA requirement for cigarette smoke interference. The sponsor evaluated the possibility of cigarette and cigar smoke interference with the device. Two alcohol-free individuals were asked to smoke approximately one half of a cigarette and cigar respectively. Within one minute after smoking, the subject took a breath alcohol reading. The subject then smoked another inhalation and repeated the test to produce a total of five trials. The Protocol device produced zero false positives in this experiment.

The sponsor has placed the following warning in their labeling:
 “Our testing has shown that this device functions accurately for at least 375 tests. Based on NIAAA studies, (www.alcoholism.about.com) this corresponds to one year of device use for most drinkers. YOU SHOULD REPLACE YOUR DEVICE ONE YEAR AFTER FIRST USE. FAILURE TO DO SO MAY CAUSE YOUR READINGS TO BE INACCURATE. If you are a heavy drinker or a heavy smoker, we strongly recommend replacing the unit sooner.”

2. Other Supportive Instrument Performance Data Not Covered Above:

None

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.