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

A. 510(k) Number:

k090067

B. Purpose for Submission:

New device for US consumer market

C. Manufacturer and Instrument Name:

KHN Solutions, LLC Bactrack Select 80 Breathalyzer

D. Type of Test or Tests Performed:

Quantitative (electrochemical fuel cell sensor)

E. System Descriptions:

1. Device Description:

   The Bactrack Select 80 breathalyzer is a self-contained unit with a sensor at the top of the unit for breath sampling. The LCD display displays a timer for countdown. There are two buttons- start button and mode button. The mode button is used to display the number of uses and aids in the re-calibration of the device. The number of uses is displayed prior to each measurement. The device is powered by two AA batteries. The device also includes six individually wrapped replaceable mouthpieces and displays up to 4 units. The display window shows the breath alcohol concentration in increments of 0.001% in the range 0.000% to 0.400% BAC. Characters are used to instruct the user and display the status of the device. The device also includes a beeper to give the user audible prompts.

2. Principles of Operation:

   The BACTRACK® Select Breathalyzer is an alcohol screening device used for the detection of alcohol in the breath. The device employs 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:

   This device has 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:

   This device is calibrated at the factory. The sponsor also recommends that the device is recalibrated after 6 to 12 months of normal use, depending on the number of tests performed and operating condition. The unit must be sent back to the manufacturer for calibration.

   Traceability:

   This device is 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

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 PT500

k080848

2. Comparison with Predicate Device:

	AlcoHAWK PT500 K080848 Q3 Innovations LLC	BACTRACK® Select Breathalyzer: S80
Similarities		
INDICATION OF USE	This device is intended to measure alcohol in the human breath. Measurements obtained by this device are used as an aid in the detection of alcohol intoxication.	SAME
MODE	Breath Alcohol Concentration	SAME
PRACTITIONER USE	Over the Counter	SAME
Blowing time	5 Seconds	SAME
Response time	3 Seconds	SAME
POWER SOURCE	2 – AA Alkaline	SAME
TYPE OF SENSOR	Fuel cell electrochemical sensor	SAME
ANATOMICAL SITE	Mouth	SAME

Mouthpiece	Replaceable, polystyrene	SAME
Warm Up Time	10-20 seconds	SAME
Operating temperature	10 - 40°C (50 - 104°F)	SAME
Measurement Range	0.000% to 0.400%	SAME
Differences		
BATTERY LIFE	200 tests	Up to 1500 tests
DOT	DOT Approved	Not currently DOT approved
DISPLAY	4 digit LCD with backlight (orange)	SAME, backlight is green
SIZE	5" x 2.63" x 1.25" (12.7 cm x 6.68 cm x 3.18 cm)	2.3 x 4.8 x 0.8 inches (5.8 x 12.2 x 2.2 cm)
WEIGHT	3.6 oz (102 g) without batteries; 5.2 oz (147 g) with batteries	4.8 oz (136 g) with mouthpiece and batteries

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

1. EN 61326 :1997 +A1:1998+A2:2001+A3:2003 Electrical equipment for measurement, control and laboratory use. EMC Requirements. General requirements.

2. EN 61000-4-2:1995 +A1:1998 +A2:2001 Testing and measurement techniques Electrostatic Discharge.

3. EN 61000-4-3:2002+A1:2002 Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test.

4. EN 61326 :1997 +A1:1998+A2:2001+A3:2003 Class B. Electrical equipment for measurement, control and laboratory use. EMC Requirements. General requirements

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 and compare to the results obtained by an evidential breath alcohol tester (the LifeLoc FC10). Seventy-six participants took their breath alcohol reading with the Bactrack Select 80 Breathalyzer and recorded the result. Immediately afterward, the participants were administered a breath alcohol

test using the professional device operated by a trained individual. The breath alcohol paired concentrations ranged from BAC of 0.000 to 0.277. Linear regression analysis of the data showed a slope of 1.062, a y-intercept of 0 and a correlation coefficient of 0.9724.

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 following table included the questions, answers and response percentages obtained from the consumer study.

Question	Strongly Disagree	Disagree	Neither agree or disagree	Agree	Strongly Agree
I found the device easy to use	0	0	0	40%	60%
I understood how to use the device after reading the instructions	0	0	0	45%	55%
I was able to easily understand and interpret the test results displayed by the device	0	1%	0	39%	60%

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 Bactrack Select 80 Breathalyzer 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 Bactrack Select 80 Breathalyzer 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 Bactrack Select 80 Breathalyzer had no false positives in this trial.

b. Temperature:

The DOT Model Specifications require testing 10 and 40^{o} C to assess any possible effects of temperature. At 10^{o} 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 Bactrack Select 80 Breathalyzer had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC.

At 40^{o} C, the requirements are identical. Again the Bactrack Select 80 Breathalyzer 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 Bactrack Select 80 Breathalyzer 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.