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

A. 510(k) Number:
  k052448

B. Purpose for Submission:
  New Device

C. Measurand:
  Breath Alcohol

D. Type of Test:
  Semi-quantitative (tin dioxide semiconductor gas sensor)

E. Applicant:
  Connectables, LLC

F. Proprietary and Established Names:
  Alcohol Tester (PB2000)

G. Regulatory Information:
  1. Regulation section:
     21 CFR § 862.3050

  2. Classification:
     Class I, reserved

  3. Product code:
     DJZ

  4. Panel:
     Toxicology (91)

H. Intended Use:
  1. Intended use(s):
     Refer to Indications for Use below

  2. Indication(s) for use:
     The Alcohol Tester device is intended to measure alcohol in human breath.
     Measurements obtained by this device are used as an aid in the detection of
     alcohol intoxication.

  3. Special conditions for use statement(s):
     Over-the-counter use

4. Special instrument requirements:
   Not applicable

I. Device Description:
The Alcohol Tester (PB2000) is a self-contained unit with an inlet for breath sampling near the top left of the unit. The two models are identical except for packaging. Users are instructed to press and hold the single button on the side of the unit for 5-15 seconds to power on the unit and warm up the sensor.   There are also three LEDs on the front of the device. The green or "Ready" LED lights when the battery power is sufficient and the device is ready to take a reading. The user provides a breath sample by exhaling into the inlet for 3 seconds. The green LED will remain lit if the breath alcohol content (BAC) is less than 0.04%, the yellow LED will light if the BAC is from 0.04 and 0.08%, and the red LED will light if the BAC is greater than 0.08%. The unit is powered by two "AAA" batteries which are installed into the battery compartment on the back of the device.

J. Substantial Equivalence Information:
1. Predicate device name(s):
   Q3 Innovations, LLC. AlcoHawk Precision

2. Predicate 510(k) number(s):
   k043188

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Same	Over the Counter
Sensor Type	Same	Semiconductor-Oxide
Construction	Same	Plastic Case with Internal Circuit Board

Differences		
Item	Device	Predicate
Result	Semi-quantitative	Quantitative
Display	Green/Yellow/Red LED	4 Digit LED
Measurement Range	Undefined – any concentration greater than 0.04% will produce a red light	0.000 - 0.400 g/dL (%)
Dimensions	2.1"x1.6"	4.25" x 2.75"
Weight	15 grams	130 grams
Power Source	Two AAA Batteries	Single 9 V Battery
Battery Life	400 Measurements	100-300 Measurements
Blow Time	3 Seconds	5 Seconds

Differences		
Item	Device	Predicate
Preheat (warm-up) Time	5-15 Seconds	15-60 Seconds

K. Standard/Guidance Document Referenced (if applicable):

The sponsor states conformance to the following standards:

1. EN 55022: 1998, Information Technology Equipment - Radio Disturbance Characteristics - Limits and Methods of Measurement-Includes Amendment A1:2000
2. EN 61000-4-2: 1995+A1: 1998+A2: 2001, Electromagnetic compatibility (EMC) - Part 4-2 : Testing and measurement techniques - Electrostatic discharge immunity test
3. EN 61000-4-3: 1996+A1:1998+A2:2001, Electromagnetic Compatibility (EMC) Part 4: Testing and Measurement Techniques Section 3: Radiated, Radio-Frequency, Electromagnetic Field Immunity Test-IEC 1000-4-3

L. Test Principle:

The Alcohol Tester (PB2000) is designed to measure deep lung air to test for the presence of alcohol in the blood. The relationship between alcohol concentration in deep lung air and blood is established by Henry's Law in a ratio of 1:2100. 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.

M. Performance Characteristics (if/when applicable):

The Connectables' device was not eligible for testing by the National Highway Traffic Safety Administration (Department of Transportation). In lieu of NHTSA testing, the sponsor collected performance data to support a claim of substantial equivalence for the device.

1. Analytical performance:
   a. *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 0.02% BAC, 20 at 0.06% BAC, and 20 at 0.010% BAC. Summary results were as follows:

Concentration	Green (less than 0.04%)	Yellow (0.04 to 0.08%)	Red (greater than 0.08%)
0.02% BAC	20	0	0
0.06% BAC	0	20	0
0.10% BAC	0	0	20

b. *Linearity/assay reportable range:*
Since this device reports a range and not an actual concentration, it is not possible to evaluate linearity.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
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 when manufactured.

d. *Detection limit:*
The NHTSA guidelines do not specifically address the detection limit of breath alcohol device but require testing at a % BAC of zero (blank reading) to assess the possibility of false positives. The sponsor tested twenty "zero" concentration samples using non-alcoholic human breath. No false positives were produced using these samples.

e. *Analytical specificity:*
The sponsor evaluated the possibility of cigarette smoke interference with the device. An alcohol-free individual was asked to smoke approximately one half of a cigarette. 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. Overall, the study involved two participants and two different cigarette brands for a total of 200 measurements. The Connectables device produced no false positives in this experiment. Other potential interferents were not evaluated with this device.

f. *Temperature*
The sponsor assessed the effect of temperature at 10 and 40° C. Twenty different devices were tested at each temperature. The concentrations chosen for testing were 0.02, 0.06, and 0.10% BAC. According to the User's Manual, if the device has been inactive for more than 24 hours, the user should take three readings and disregard the first two. Only the third reading should be used. When this instruction was followed, the following results were obtained:

Temperature	Concentration (%BAC)	Green/Yellow/Red
40° C	0.02	20/0/0
40° C	0.06	0/20/0
40° C	0.10	0/0/20
10° C	0.02	20/0/0
10° C	0.06	0/20/0
10° C	0.10	0/0/20

g. *Vibration/Drop Testing*

The sponsor performed vibration testing per NHTSA specifications at concentrations of 0.02, 0.06, and 0.10% BAC. Twenty separate devices were used for each trial. Trial A involved vibrating the devices through a frequency range of 10 to 30 Hz at an amplitude of 3.0 mm. Results were as follows:

Concentration (%BAC)	Green/Yellow/Red
0.02	20/0/0
0.06	0/20/0
0.10	0/0/20

Trial B involved vibrating the devices through a frequency range of 30 to 60 Hz at an amplitude of 1.5 mm. Results were as follows:

Concentration (%BAC)	Green/Yellow/Red
0.02	20/0/0
0.06	0/20/0
0.10	0/0/20

h. *Assay cut-off:*

The colored lights on the Breathalyzer (PB1000) and Alcohol Tester (PB2000) are interpreted as follows:

No lights illuminated: Battery low
Green light illuminated: BAC is less than 0.04%
Yellow light illuminated: BAC is in the range of 0.04 to 0.08%
Red light illuminated: BAC is greater than 0.08%

2. Comparison studies:
   a. *Method comparison with predicate device:*
   The sponsor conducted a consumer study comparing the Alcohol Tester PB2000 to the predicate device. The purpose of the study was to determine if consumers could correctly operate and interpret the device using only the supplied User's Manual, and to compare the results to the predicate device. There were 27 paired comparisons, and the reported age range of the volunteers was from 21 to 56 years of age. There were 18 men and 9 women who participated in the trial. Each participant took their own breath alcohol

reading with the Alcohol Tester and recorded the result. Immediately afterward, the participants provided another breath sample, which was analyzed using the predicate device operated by a trained individual. The breath alcohol concentrations ranged from a BAC of 0.00% to 0.35% by the predicate device.

Based on the interpretation chart in the labeling, 21 out of 27 samples produced a concentration range on the Alcohol Tester that included the specific concentration measured by the predicate. For 5 samples the Connectables device gave a concentration range lower than the predicate device result. For 1 sample, the Connectables device gave a concentration range higher than the predicate. The six discrepant results are presented in the table below:

Connectables Result	Predicate Device Result	Connectables vs. predicate
Yellow	0.09	Lower
Yellow	0.09	Lower
Yellow	0.12	Lower
Yellow	0.10	Lower
Yellow	0.09	Lower
Red	0.08	Higher

After the study, participants were asked questions about the ease of use of the device:

Question	Participants Responding Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
I found the device easy to use	0	0	0	5	22
I understood the instructions and how to interpret the results	0	0	1	5	21

Finally, the participants were asked to interpret their result based on the instructions in the labeling, and all of the participants correctly identified the range of concentrations listed in the labeling.

b. *Matrix comparison:*
   Not applicable. This device is intended for one sample matrix only.

3. Clinical studies:
   a. *Clinical Sensitivity:*
      Not applicable.

   b. *Clinical specificity:*
      Not applicable.

   c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off**:**
   Not applicable.

5. Expected values/Reference range:
   Using these types of devices, alcohol is not detectable in the breath of persons who have not ingested alcohol.

N. Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.