

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

A. 510(k) Number:

k052804

B. Purpose for Submission:

New Device

C. Measurand:

Breath Alcohol

D. Type of Test:

Quantitative (electrochemical fuel cell type alcohol sensor)

E. Applicant:

OmegaPoint Systems, LLC

F. Proprietary and Established Names:

BreathKey™ Model g10 and BreathKey™ Model g30X Personal Breath Alcohol Tester

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.3050
2. Classification:
Class I
3. Product Code:
DJZ
4. Panel:
Toxicology (91)

H. Intended Use:

1. Intended use(s):
Refer to Indications for use.
2. Indication(s) for use:
OmegaPoint Systems Personal Breath Alcohol Tester BreathKey™ Model g10 and BreathKey™ Model g30X are indicated for use to measure alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication. BreathKey™ Model g30X transmits the BAC results to an interlock receiver installed in a motor vehicle.
3. Special condition for use statement(s):
Over-the-counter use
4. Special instrument Requirements:
Not Applicable

I. Device Description:

The **OmegaPoint Systems BreathKey™ Model g10 and Model g30X** are identical, except that the **Model g30X** contains an additional internal component that transmits the breath alcohol level to a remote receiver that is intended to control the ignition of a motor vehicle.

On the front of both devices is a small speaker, a single ON/OFF button, and the LCD display. The mouthpiece is located at the top of the unit, and the battery access cover is located on the back. To perform a breath test, the user presses the single button on the front of the device. The unit turns on and displays the results of the previous breath test. WAIT may be displayed for a few seconds while the device prepares for a reading. When the device displays BLOW, the user is instructed to blow into the mouthpiece for four seconds in order to obtain a valid deep lung breath sample. If an appropriate breath sample is provided, the device will display WAIT for a few seconds while the blood alcohol concentration is calculated.

J. Substantial Equivalence Information:

1. Predicate device name(s):
AlcoMate CA2000 Digital Alcohol Detector
Intoxilyzer S-D5
2. Predicate K number(s):
k041334

The Intoxilyzer S-D5 is an evidential breath alcohol device which has been tested by the National Highway Traffic Safety Administration (NHTSA) and appears on their Conforming Products List. It has not been cleared through the FDA 510(k) process but is considered a “gold standard” and is therefore an appropriate predicate device.

3. Comparison with predicate:

Similarities			
Item	Device	Predicate	Predicate
Name and Model Number	OmegaPoint Personal Breath Alcohol Tester Model g10 and g30X	Professional Intoxilyzer Model S-D5	AlcoMate CA2000
Intended Use/Indications for Use	Same	Intended to measure alcohol in human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.	Intended to measure alcohol in human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.
Sampling Time	4 seconds	4 seconds	5 seconds
Size	2 3/8" H x 1 3/8" W x 9/16" D	4 3/4" H x 2 1/2" W x 1 1/4" D	5" H x 2 1/2" W x 1" D

Differences			
Item	Device	Predicate	Predicate
Name and Model Number	OmegaPoint Personal Breath Alcohol Tester Model g10 and Model g30X	Professional Intoxilyzer Model S-D5	AlcoMate CA2000
Sensor Type	Electrochemical Fuel Cell	Electrochemical Fuel Cell	Semi-conductor-Oxide Sensor
Intended User	General Public	Law Enforcement	General Public
Weight	20 grams	120 grams	200 grams
Power Source	3 Volt Battery, Non-replaceable	2 AAA Batteries, Replaceable	9 Volt Battery, Replaceable
Mouthpiece	Integrated, non-replaceable	Replaceable	Replaceable
Warmup Time	3 seconds	20 seconds	20 seconds
Measuring Range	0.00 – 0.20%	0.00 – 0.40%	0.00 – 0.40%

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

The sponsor states conformance to the following standard:

CLSI EP10-A2, Preliminary Evaluation of Quantitative Clinical Laboratory Methods; Approved Guideline – Second Edition

L. Test Principle:

The sensor has two electrodes in which platinum is fixed to a porous substrate. The porous substrate operates as a gas permeable membrane and structural support for the electrode. The electrodes are located on the inside surface of the membrane where they make contact with sulfuric acid as an electrolyte. When ethanol from a deep lung air sample diffuses through the porous membrane to reach the working electrode, the ethanol is oxidized or reduced at the interface of the working electrode and the electrolyte. That reaction generates an electrical current that is proportional to the concentration of the ethanol.

The amplifier on the circuit board of the device converts the electrical current from the alcohol sensor into a voltage, and then sends the voltage to the microprocessor. The microprocessor converts this voltage into a number that the internal software can then use as a basis for the calculation of the blood alcohol concentration (BAC). Once the BAC is calculated, the microprocessor sends the BAC value to the LCD display.

This device uses an algorithm to convert deep lung breath alcohol concentration to blood alcohol concentration according to the relationship established by Henry's Law.

M. Performance Characteristics (if/when applicable):

The g10 and g30X devices were not eligible for testing by the National Highway Traffic Safety Administration. In lieu of NHTSA testing, the sponsor collected performance data to support a claim of substantial equivalence for the devices.

1. Analytical performance:

a. *Precision/Reproducibility:*

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

g10 model

The sponsor performed 20 tests at 0.00% BAC, 20 at 0.02% BAC, and 20 at 0.08% BAC. Summary results were as follows:

BASS Concentration (% BAC)	0.00	0.02	0.08
Number of Replicates	20	20	20
Mean	0.00	0.020	0.084
Standard Deviation	0.00	0.004	0.005
Coefficient of Variation (%)	0.0	18.3	5.6

g30X model

The sponsor performed a more extensive study based on CLSI guideline EP10-A2. Summary results were as follows:

BASS Concentration (% BAC)	0.00	0.02	0.08
Number of Replicates	20	20	20
Mean	0.000	0.018	0.072
Standard Deviation	0.00	0.002	0.007
Coefficient of Variation (%)	0.0	11.7	9.2

b. Linearity/assay reportable range:

This device will report concentrations from 0.00 to 0.20% BAC. Since accuracy and precision testing was conducted at concentrations of 0.00, 0.020, and 0.080 only, true linearity was not evaluated.

c. Traceability (controls, calibrators, or method):

This device is traceable to a commercially available certified alcohol reference solution at a concentration of 0.08% BAC. This solution is used to calibrate the devices during manufacture.

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 included a zero concentration sample in their precision studies above. Non-alcoholic human breath was used as the sample. Neither model produced any false positives when measuring zero concentration 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. The OmegaPoint device had no positive results.

Other potential interferents were not evaluated with this device.

f. Temperature:

The sponsor assessed the effect of temperatures over the operating range (10 to 40° C) of the devices. (If the device is powered on at a temperature outside the operating range, an error code “HOT” or “COLD” will be displayed and the device will not operate.) Ten different devices were tested at each temperature. All testing was done at a BAC of 0.08%. Summary results were as follows:

Temperature (°C)	10	20	30	40
Number of Replicates	10	10	10	10
Mean	0.088	0.077	0.075	0.072
Standard Deviation	0.009	0.007	0.010	0.009
Coefficient of Variation (%)	9.8	9.0	13.6	13.5

g. Vibration/Drop Testing:

Drop testing was performed on the g10 model at a BAC of 0.08%. Prior to testing, the device was dropped 10 times from a height of 5 feet onto a hard surface. After the 10 drops, 10 readings were taken. Summary results were as follows:

Mean	0.082
Standard Deviation	0.006
Coefficient of Variation (%)	7.4

Drop testing was not performed separately on the g30X model.

h. Assay Cutoff:

In their labeling, the sponsor states that drivers may be impaired at a BAC of 0.04% or even lower and that it is never safe to drink any amount of alcohol and drive.

The g30X model can be used in conjunction with a remote receiver (interlock device) that is intended to control the ignition of a motor vehicle. The cutoff concentration is set by the interlock device. The sponsor states that the cutoff concentration will be set at 0.02% BAC.

2. Comparison studies:

a. *Method comparison with predicate device:*

The accuracy of this device is addressed in the precision section above. In addition, the sponsor conducted a method comparison study comparing the Model g10 to a professional breath alcohol device. The purpose of the study was to determine if the participants could operate the device correctly and interpret the results using only the supplied Operation Manual, and to compare the results to the professional device. There were 5 participants and a total of 9 paired comparisons. Each participant took their own breath alcohol reading with the Model g10 and recorded the result. Immediately afterward, the participants were administered a breath alcohol test using an Intoximeter S-D5 operated by a trained individual. The breath alcohol concentrations ranged from a BAC of 0.000 to 0.066 (by the professional device). Simple linear regression analysis of the data shows a slope of 0.99, a y-intercept of 0.00, and a correlation coefficient of 0.99.

The sponsor also conducted a usability and readability study in which participants were asked to use the device and read the Operation Manual prior to filing out a questionnaire. There were 51 participants including the 5 participants who provided a breath sample above. The results are presented below:

Question	Percentage answering correctly	Correct response (explanatory text in parentheses)
Can this device be used to determine if you can safely operate a motor vehicle?	61%	Yes (The sponsor's Operation Manual states "Do not use this device to determine if you can safely operate a motor vehicle or machinery of any kind. ")
How long after eating or drinking should you wait before taking a breath test?	84%	20 minutes
Is it possible for this device to give a positive reading after eating or drinking something other than an alcoholic drink?	86%	Yes
About how long do you need to blow into the device?	71%	4 seconds
If a test gives a positive reading for alcohol, how long will the device make you to wait before taking the next test?	76%	3 minutes
What is the maximum reading the device can give?	75%	0.200
What is the best way to clean the device?	96%	With a damp cloth
Overall, how easy would you say the operation manual is to understand?	-----	Very Easy: 67% Between Very Easy and Somewhat Easy: 29% Somewhat Easy: 4%

b. Matrix comparison:

N/A. This device is intended for one sample matrix only.

3. Clinical studies:

a. Clinical sensitivity:

N/A

b. Clinical specificity:

N/A

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

4. Clinical cut-off:
N/A
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.