

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

k063443

B. Purpose for Submission:

New device.

This device has met the US Department of Transportation requirements for evidential breath measurement devices.

C. Measurand:

Breath Alcohol

D. Type of Test:

Quantitative (electrochemical fuel cell sensor)

E. Applicant:

Drager Safety AG & Co. KGaA

F. Proprietary and Established Names:

Drager Alcotest 6510

Blood Alcohol Detector (through relationship between breath and blood alcohol)

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.

2. Indication(s) for use:

The Drager Alcotest 6510 is a device intended to measure alcohol in human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.

3. Special conditions for use statement(s):

Over the counter use

4. Special instrument requirements:

Not applicable.

I. Device Description:

The Drager Alcotest 6510 is a self-contained unit with a disposable mouthpiece for breath sampling. The mouthpiece is snapped into a receptacle at the top of the unit. Below the mouthpiece receptacle is an indicator light which glows red or green. The graphics display screen displays the user's blood alcohol equivalent concentration to three decimal places as well as text prompts and error messages. Below the display are up, down, and "OK" buttons for menu navigation. Two AA batteries or a single rechargeable battery are inserted into the compartment on the back of the unit. The device is powered on by depressing the OK button for approximately 1 second until the start window is displayed. After 2 seconds WAIT will appear on the display, followed by READY and a short beep when the device is ready to accept a measurement. As the user exhales into the mouthpiece, the device monitors breath volume and blowing time. If the flow of the breath sample is sufficient, the indicator light glows green and there is a continuous beep. When the instrument verifies that the breath volume is also sufficient, the green light goes out and the beeping stops, and the concentration appears in the display.

J. Substantial Equivalence Information:1. Predicate device name(s):

Breathkey Models g10/g30x

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

k052804

3. Comparison with predicate:

Similarities		
Item	Alcotest 6510	Predicate
analyte	Same	Breath Alcohol
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.
Measurement type	Same	Electrochemical Fuel Cell
Intended User	Same	General Public (Over the Counter Use)

Differences		
Item	Alcotest 6510	Predicate
Measuring Range	0.00 – 0.500% BAC	0.00 – 0.200% BAC
Dimensions	5 1/2“ H x 3 1/8 “ W x 1 1/3” D	2 3/8“ H x 1 3/8 “ W x 9/16” D
Weight	200 grams	20 grams
Power Source	2 AA batteries or rechargeable NiMH battery	9 volt battery
Mouthpiece	Replaceable	Integrated, nonreplaceable

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

The sponsor states conformance to the following standards:

1. Department of Transportation National Highway Traffic Safety Administration [Docket No. NHTSA-2006-24964] Highway Safety Programs; Model Specifications for Devices to Measure Breath Alcohol
2. EN 61000-6-2:2001 (IEC 61000-6-2:1999, modified) Part 6-2: Generic Standards Immunity for industrial environments
3. EN 61000-6-3:2001 (IEC 61000-6-3:1996, modified) Part 6-3: Generic standards: Emission standard for residential, commercial and light-industrial environments.
4. EN 55022:1998 + Corrigendum July 2003 + A1:2000 +Corrigendum April 2003 + A2:2003 (IEC/CISPR 22:1997 + A1:2000 + A2:2002) Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement
5. CISPR 16-2-3: 2003 Specification for radio disturbance and immunity measuring apparatus and methods - Part 2-3: Methods c f measurement of disturbances and immunity - Radiated disturbance measurements
6. EN 61000-3-2:2000 (IEC 61000-3-2: 2000 modified) Part 3-2: Limits for harmonic currents
7. EN 61000-3-3:1995 + Corr.:1997 +A1:2001 (IEC 61000-3-3:1994 +A1:2001) Part 3-3: Limitation of voltage fluctuations and flicker
8. EN 61000-4-2:1995 +A1:1998 +A2:2001 (IEC 61000-4-2:1995 +A1:1998 +A2:2000) Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test
9. EN 61000-4-3:2002 +A1:2002 (IEC 61000-4-3:2002 +A1:2002) Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
10. EN 61000-4-4:1995 +A1:2001 +A2:2001 (IEC 61000-4-4:1995+A1:2000 +A2:2001) Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test
11. EN 61000-4-5:1995 +A1:2001 (IEC 61000-4-4:1995+A1:2000) Part 4-5: Testing and measurement techniques - Surge immunity test
12. EN 61000-4-6:1995 +A1:2001 (IEC 61000-4-5:1995 +A1:2000) Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio- frequency fields
13. EN 61000-4-8:1993 +A1:2001 (IEC 61000-4-8:1993 +A1:2000) Part 4-8: Testing

and measurement techniques - Power frequency magnetic field immunity test

14. EN 61000-4-11:1994 +A1:2001 (IEC 61000-4-11:1994 +A1:2000) Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity test

L. Test Principle:

The electrochemical fuel cell alcohol sensor in this device consists of a plastic housing, a membrane with positive and negative electrodes, and platinum leads. As the alcohol gas passes through the cell, it initiates a chemical reaction resulting in a voltage change. This voltage change can then be converted to a breath alcohol concentration which in turn is converted to a blood alcohol concentration.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The precision and accuracy of this device has previously been demonstrated through testing required by the US Department of Transportation. For precision and accuracy, these requirements (referred to as Model Specifications) consist of 10 trials each at Blood Alcohol Concentrations (BAC) of 0.000, 0.020, 0.040, 0.080, 0.160, and 0.300. Blood Alcohol Concentrations 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 each concentration are: standard deviation ≤ 0.0042 , systematic error (mean – target BAC) $\leq \pm 0.005$ BAC or 5%, whichever is greater. The 0.000 BAC trial has the additional requirement that there be no single result greater than 0.005. The BAC 0.300 sample is for informational purposes only and does not have any performance requirements.

The Drager Alcotest 6510 met all of the applicable NHTSA requirements for precision and accuracy.

b. Linearity/assay reportable range:

This device will report concentrations from 0.00 to 0.500% BAC. However, the DOT Model Specifications require accuracy and precision testing up to a concentration of 0.300 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.

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

This device is traceable to a commercially available certified alcohol reference solution. The sponsor states that the device can be calibrated at a concentration between 0.080 and 0.150% BAC. The acceptance criterion for accuracy is $\pm 5\%$ or $\pm 0.005\%$ BAC, whichever is greater, throughout a calibration period.

d. *Detection limit:*

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. Refer to section M.1.a above.

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 according to the manufacturer's instructions. The subject then smoked another inhalation and repeated the test to produce a total of five trials. The study included two participants, two brands of cigarettes, and a total of 20 measurements. The device had no positive results. Other potential interferents were not evaluated with this device.

Temperature:

When evaluated by the NHTSA / DOT, the device was tested at a concentration of 0.080% BAC at a temperature of 10, 20, 30, and 35 degrees Celsius. The mean % BAC from the four temperature trials ranged from 0.078 to 0.080% BAC and the standard deviations ranged from 0.0007 to 0.0021. However, there are no performance requirements for testing at different temperatures. This information is reported for the information of the potential user only.

Vibration:

Evidential devices are also subject to vibration testing to assess any possible vibrational effects at a concentration of 0.080% BAC from 10 to 30 hertz and from 30 to 60 hertz. This trial is repeated 10 times and the mean, standard deviation, and standard error are calculated. The acceptance criteria are: standard deviation 0.0042 or less and standard error $\pm 0.005\%$ BAC or 5%, whichever is greater. The device satisfied the performance requirements for vibration testing.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

The sponsor performed a consumer study to determine if consumers could correctly use and interpret the device using only the supplied User's Manual, and to compare the results to a professional device (the Intoxilyzer S-D5). There were 45 paired comparisons, and the volunteers ranged in age from 21 to 76 years of age. Each participant took their breath alcohol reading with the Drager Alcotest 6510 and recorded the result. Immediately afterward, the participants were administered a breath alcohol test using an Intoxilyzer S-D5 operated by a trained individual. The breath alcohol concentrations ranged from BAC of 0.000 % to 0.097 % (by the Intoxilyzer S-D5). Linear regression analysis of the data showed a slope of 0.9905, a y-intercept of 0 and a correlation coefficient of 0.9995. After the study, participants were asked questions about ease of use and interpretation. The results are presented below:

Participant Information:	
Gender	Number
M	25
F	20
Total	45

Age Range	Number	Male	Female	School	University
21-29	15	9	6	2	13
30-39	6	2	4	2	4
40-49	9	6	3	5	4
50-59	8	4	4	2	6
60-69	4	3	1	4	0
70-79	3	1	2	2	1

Questions:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
The Dräger Allocates 6510 instructions are easy to understand.	0	0	0	17	28
I understood how to use the Dräger Alcotest 6510 after reading the instruction manual.	0	0	0	9	36
I was able to operate the Dräger Alcotest 6510 easily.	0	0	1	11	33
I was able to understand and interpret the test results displayed by the Dräger Alcotest 6510.	0	0	0	5	40

Q1: "The Dräger Alcotest 6510 instructions are easy to understand."

Q1	M	F	School	Univ	21-29	30-39	40-49	50-59	60-69	70-79	Total
Strong agree	18	10	7	22	14	2	7	3	1	1	28
Agree	7	10	10	6	1	4	2	5	3	2	17
Neither agree or disagree	0	0	0	0	0	0	0	0	0	0	0
Disagree	0	0	0	0	0	0	0	0	0	0	0
Strong disagree	0	0	0	0	0	0	0	0	0	0	0
Total	25	20	17	28	15	6	9	8	4	3	45

Q2: "I understood how to use the Dräger Alcotest 6510 after reading the instruction manual."

Q2	M	F	School	Univ	21-29	30-39	40-49	50-59	60-69	70-79	Total
Strong agree	21	15	10	26	15	4	7	7	1	2	36
Agree	4	5	7	2	0	2	2	1	3	1	9
Neither agree or disagree	0	0	0	0	0	0	0	0	0	0	0
Disagree	0	0	0	0	0	0	0	0	0	0	0
Strong disagree	0	0	0	0	0	0	0	0	0	0	0
Total	25	20	17	28	15	6	9	8	4	3	45

Q3: "I was able to operate the Dräger Alcotest 6510 easily."

Q3	M	F	School	Univ	21-29	30-39	40-49	50-59	60-69	70-79	Total
Strong agree	18	15	10	23	13	3	9	5	1	2	33
Agree	6	5	7	4	2	3	0	2	3	1	11
Neither agree or disagree	1	0	0	1	0	0	0	1	0	0	1
Disagree	0	0	0	0	0	0	0	0	0	0	0
Strong disagree	0	0	0	0	0	0	0	0	0	0	0
Total	25	20	17	28	15	6	9	8	4	3	45

Q4: "I was able to understand and interpret the test results displayed by the Dräger Alcotest 6510."

Q4	M	F	School	Univ	21-29	30-39	40-49	50-59	60-69	70-79	Total
Strong agree	24	16	13	27	15	5	9	7	2	2	40
Agree	1	4	4	1	0	1	0	1	2	1	5
Neither agree or disagree	0	0	0	0	0	0	0	0	0	0	0
Disagree	0	0	0	0	0	0	0	0	0	0	0
Strong disagree	0	0	0	0	0	0	0	0	0	0	0
Total	25	20	17	28	15	6	9	8	4	3	45

b. Matrix comparison:

Not applicable.

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. Instrument Name:

Dräger Safety AG & Co. KGaA Alcotest 6510 Breath Alcohol Test Instrument

O. System Description:

1. Modes of Operation:

The Drager Alcotest 6510 is a self-contained unit with a disposable mouthpiece for breath sampling. The mouthpiece is snapped into a receptacle at the top of the unit. Below the mouthpiece receptacle is an indicator light which glows red or green. The graphics display screen displays the user's blood alcohol equivalent concentration to three decimal places as well as text prompts and error messages. Below the display are up, down, and "OK" buttons for menu navigation. Two AA batteries or a single rechargeable battery are inserted into the compartment on the back of the unit. The device is powered on by depressing the OK button for approximately 1 second until the start window is displayed. After 2 seconds WAIT will appear on the display, followed by READY and a short beep when the device is ready to accept a measurement. As the user exhales into the mouthpiece, the device monitors breath volume and blowing time. If the flow of the breath sample is sufficient, the indicator light glows green and there is a continuous beep. When the instrument verifies that the breath volume is also sufficient, the green light goes out and the beeping stops, and the concentration appears in the display.

2. Software:

FDA has reviewed the applicant's Hazard Analysis and software development processes for this line of product types:

Yes X or No

3. Specimen Identification:

There is no mechanism to identify the specimen.

4. Specimen Sampling and Handling:

The user provides a breath sample by exhaling into the device. The instrument checks for adequate breath flow and volume during sampling.

5. Calibration:

The device is calibrated at the factory and sent directly to the end user. The sponsor recommends a recalibration interval of six months (typical) to twelve

months (required) based on calibration stability data collected internally. The unit must be sent back to the factory for calibration.

6. Quality Control:

There are no external quality controls available for the consumer version of this device.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

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