510(k) SUMMARY

MAR 11 2008

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K063443

1. **Submitter Information**
   Name: Dräger Safety AG & Co. KGaA
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   Telephone Number: +49 (0)451-882-4713
   Facsimile Number: +49 (0)451-882-7-4713
   Contact Person: Stefan Steinmeyer
   Date: November 13, 2006

2. **Device Information**
   Trade or Proprietary Name: Dräger Alcotest® 6510
   Common or Usual Name: Breath-Alcohol Test
   Classification Name: Devices, Breath Trapping, Alcohol (per 21 CFR section 862.3050).

3. **Predicate Device**
   Dräger Alcotest 6510 is equivalent to the following:

   OmegaPoint Systems Personal Breath Alcohol Tester BreathKey™ Model G10 and BreathKey™ Model G30X (K052804)

4. **Indications for Use**
   The Dräger Alcotest 6510 is an apparatus for indicating the presence of alcohol in the breath.

5. **Device Description**
   The Dräger Alcotest 6510 is designed to measure deep lung air to determine the level of alcohol in the blood. The alcohol sensor is of the electrochemical fuel cell type. As the user's breath moves through the sensor, the sensor generates an electrical current that is proportional to the concentration of ethanol in the breath.

6. **Safety and Effectiveness**
The results of bench, DOT and user testing indicates that the new device is as safe and effective as the predicate device. A clinical trial was performed to establish that the user could read and understand the instructions provided, and properly use the device.

7. **Substantial Equivalence Determination**
Comparison to Predicate Devices:

Similarities			
Parameter	Dräger Alcotest 6510	Professional Intoxilyzer Model S-D5	Breathkey™
Indications for Use	Determining breath alcohol level	Determining breath alcohol level	Determining breath alcohol level
Construction	Plastic case, button, display, internal circuitry with microprocessor and ethanol sensor	Plastic case, button, display, internal circuitry with microprocessor and ethanol sensor	Plastic case, button, display, internal circuitry with microprocessor and ethanol sensor
Sensor	Electrochemical fuel cell	Electrochemical fuel cell	Electrochemical fuel cell
Anatomical Site	Mouth	Mouth	Mouth
Test Sample	Human Breath	Human Breath	Human Breath
DOT approval	Yes	Yes	No

Differences			
Parameter	Dräger Alcotest 6510	Professional Intoxilyzer Model S-D5	Breathkey™
Where Used	Police cruiser, prison, hospital, in public	Law enforcement	General public
Measurement Range	0.00-0.500%	0.00-0.40%	0.00-0.20%
Blowing Time	3-30 sec.	4 seconds	4 seconds
Mouthpiece	Replaceable	Replaceable	Integrated, non-replaceable
Power source	2 x 1.5V alkaline (AA) batteries, replaceable	2 AAA batteries, replaceable	3 Volt battery, non-replaceable
Warm-up time	6 seconds	20 seconds	3 seconds
Size	5 ½"W x 2 4/5 "H x 1 ¼"D	2 ½"W x 4 ¾"H x 1 ¼"D	1 3/8"W x 2 3/8"H x 9/16"D
Weight	195 grams	20 grams	120 grams

8. Conclusions

After analyzing bench tests, electrical safety, results of DOT conformance testing, and user testing data, it can be concluded that Dräger Alcotest 6510 is as safe and effective as the predicate and comparative devices. User studies showed that intended users of the device could read and understand the instructions, could properly use the device and obtain results that were comparable to those provided by a predicate device administered by a trained individual.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Dräger Safety
c/o Ms. Eve Damiano
Damiano Consulting Associates, Inc.
333 Alpine Street
Emmaus, PA 18049

MAR 11 2008

Re: k063443
Trade/Device Name: Dräger Alcotest 6510 Breath Alcohol Test
Regulation Number: 21 CFR§862.3050
Regulation Name: Breath-alcohol test system
Regulatory Class: DJZ
Product Code: Class I, reserved
Dated: February 09, 2008
Received: February 11, 2008

Dear Ms. Damiano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063443

Device Name: Dräger Alcotest 6510

Indications For Use:

The Dräger 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.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K063443