DEC 9 2005

K052804

16. 510(k) Summary

Date

July 29, 2005

Owner

OmegaPoint Systems, LLC
Ed Gollar
1077 Celestial Street
Suite 400
Cincinnati, OH 45202
Telephone: 513-241-7540
Fax: 513-241-7050

Trade Name

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

Common Name

Device, Breath Trapping Alcohol
Medical Specialty: Toxicology
Product Code: DJZ
21 CFR: 862.3050

Predicate Device(s)

AlcoMate CA2000 Digital Alcohol Detector manufactured by KHN Solutions LLC
510(k) Premarket Notification number: K041334
FDA Product Code: DJZ

Intoxilyzer S-D5, manufactured by CMI, Inc
DOT approved device
69 FR 42237 (See Appendix 1.0)

Device Description

The **OmegaPoint Systems BreathKey™ Model g10 and BreathKey™ Model g30X** Personal Breath Alcohol Testers are designed to measure deep lung air to determine the level of alcohol in the blood. **BreathKey™ Model g30X** is identical to **Model g10** except that **Model g30X** transmits the Blood Alcohol Content (BAC) results by way of a radio frequency signal to an interlock receiver installed in a motor vehicle.

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.

Intended Use

The **OmegaPoint Systems BreathKey™ Model g10 and BreathKey™ Model g30X** are intended 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

Substantial Equivalence Conclusion

Product bench testing indicates substantial equivalence to both predicate devices. The comparison testing of the Intoxilyzer S-D5 DOT approved device, the AlcoMate CA2000 and the OmegaPoint Systems BreathKey™ Model g10 and BreathKey™ Model g30X with the inclusion of DOT requirements indicate equivalence to the predicates regarding safety and efficacy.

A clinical trial designed to assess user readability and understandability of the Operation Manual show safety regarding consumer use of the device.

Summary of Substantial Equivalence

Feature	AlcoMate CA2000 K041334	Professional Intoxilyzer Model S-D5, Evidential Breath Alcohol Device	OmegaPoint Personal Breath Alcohol Tester Model g10 and Model g30X
Indication for USE	Measure alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.	Determining breath alcohol level	Determining breath alcohol level. 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.
Intended User	General Public	Law enforcement	General Public
Where Used	Home, In public	Police cruiser, police station	Home, In public
Construction	Plastic case with internal circuit board, display, internal circuitry with 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	Semi-conductor-Oxide Sensor	Electrochemical fuel cell	Electrochemical fuel cell
Size	3 ½"W x 5"H	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	200 grams	120 grams	20 grams
Sampling Time	5 sec	4 sec	4 sec
Mouthpiece	Replaceable	Replaceable	Integral
Power Source	9 Volt Alkaline Battery, replaceable	2 AAA batteries, replaceable	3V lithium battery, permanent
Warm-up Time	20 sec	20 sec	3 sec
Display	3 Digit LED	3 Digit LED	3 Digit and 4 Characters LCD
Accuracy	+/- 0.01% BAC @ 0.10%	0.005% BAC @ up to 0.10%	+/- 0.0014% BAC @ 0.80%
Measurement Site	Mouth	Mouth	Mouth
MODE	Breath Alcohol Concentration	Breath Alcohol Concentration	Breath Alcohol Concentration
Measurement Range	0.00 – 0.40%	0.00 – 0.40%	0.000 – 0.200%
DOT Approval	YES	YES	NO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OmegaPoint Systems, LLC
c/o Ewe Degenhardt
TUV America
10040 Mesa Rim Road
San Diego, CA 92121

DEC 9 2005

Re: k052804
Trade/Device Name: OmegaPoint Systems Personal Breath Alcohol Tester
BreathKey™ Model g10 and Breathkey™ Model g30X

Regulation Number: 21 CFR 862.3050
Regulation Name: Breath-alcohol test system
Regulatory Class: Class I
Product Code: DJZ
Dated: December 7, 2005
Received: December 8, 2005

Dear Mr. Degenhardt:

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) 276-0484. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

5. Indications for Use

510(k) Number (if known): K052804

Device Name: **OmegaPoint Systems Personal Breath Alcohol Tester BreathKey™ Model g10 and BreathKey™ Model g30X**

Indications 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

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X___ (21 CFR 807 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) K052804