K062971

SECTION 5. 510(k) SUMMAR Y

5.1 Date: September 28, 2006

5.2 Submitter:

DEC 18 2006

Name: Akers Biosciences, Inc

Address: 201 Grove Road

Thorofare, New Jersey, 08086

Telephone: 856-848-8698

Contact: Barbara A. Bagby

5.3 Device:

Trade or Proprietary Name:

Breath Alcohol ☑® *.02* Detection System

BreathScan® .02 Breath Alcohol Detection System

Common or usual Name: Breath-alcohol test

Classification Name: Devices, Breath Trapping, Alcohol

Product Code: DJZ

Regulation Number: 862.3050

5.4 Predicate Device:

Breath Alcohol ☑® *.02* Detection System and BreathScan® .02 Breath Alcohol Detection System are equivalent to: CONNECTABLES® Alcohol Tester manufactured by Connectables, LLC in Waukegan, IL (K052448).

5.5 Indications for Use

The Breath Alcohol ☑® *.02* Detection System and BreathScan® .02 Breath Alcohol Detection System are *in vitro* medical devices that qualitatively detect the presence of alcohol in the human breath. The test system detects equal to or greater than 0.02 percent breath alcohol. The system is used only as a screening device and is only an indication of the possible presence of alcohol in the blood of the test subject.

5.6 Description of the device

The Breath Alcohol ■® *.02* Detection System and BreathScan® .02 Breath Alcohol Detection System are a visual qualitative test for alcohol in the human breath. The Breath Alcohol ■® *.02* Detection System and BreathScan® .02 Breath Alcohol Detection System consist of a self-contained electronic analyzer to qualitatively detect the presence of alcohol in the human breath. It is a re-usable device designed for use with a specific lot of Breath Alcohol ■® *.02* or BreathScan® .02 Detectors. The detectors are disposable screening devices designed for one time use. The Breath Alcohol ■® *.02* and BreathScan® .02 Electronic Analyzers enable the user to read or interpret their Breath Alcohol ■® *.02* or BreathScan® .02 Detectors charged by human breath. The system provides an indication of the possible presence of alcohol in the blood of the test subject.

The detectors contains chemicals that change color in the presence of alcohol vapors) utilizing the patented technology (US Patent No. 4,740,475). The Detector consists of two parts. One part is a glass capsule containing light yellow crystals that change color when exposed to alcohol vapors. The other part is a plugged, plastic tube with an opening to blow into while running the test.

If alcohol is present, the crystals will change from yellow to light green/blue. How many crystals turn color will depend on the cut-off of the Detector and how much alcohol is in the breath.

The yellow crystals in the Detector are coated with potassium dichromate ($K_2Cr_2O_7$) and sulfuric acid (H_2SO_4). The amount of these indicator chemicals is adjusted according to the selected cutoff of the Detector. A color change is produced when alcohol vapors are oxidized to acetic acid and the indicator chemicals change to chromium sulfate [$Cr_2(SO_4)_3$]. The majority of crystals change from yellow to light aqua (greenish-blue/bluish-green) when alcohol vapors are present at a level equal to or exceeding the cutoff of the Detector.

The blow bags are re-usable and serve as a method to assure that the subject has blown through the Detector with adequate air. With the Breath Alcohol ■® *.02* Detection System, this is required (DOT/NHTSA compliance) and is listed as an option in the BreathScan® .02 Breath Alcohol Detection System.

The Breath Alcohol ■® *.02* and BreathScan® .02 Electronic Analyzers are self-contained, sealed devices where the Breath Alcohol ■® or BreathScan® Detector charged with human breath is inserted into the device to begin the reading process. The internal make-up of the Electronic Analyzer is the same for both models. The only difference is how the detector is positioned or inserted into the device. Using the Breath Alcohol ■® *.02* Detection System, the detector is inserted into a sample port; whereas using the BreathScan® .02 Breath Alcohol Detection System, the detector is placed in a nested holder.

The Electronic Analyzer automatically turns on and the lights will flash instantaneously, indicating the respective result. The device comes pre-calibrated to the user for the cut-off sensitivity of the Breath Alcohol ☑® *.02* or BreathScan® .02 Detector lot being "read" in the analyzer. A negative result is indicated by a continuously flashing green LED and a positive result is indicated by a continuously flashing red LED.

5.7 Safety and Effectiveness

The bench test and user testing data indicated that the Breath Alcohol ☑® *.02* Detection System and BreathScan® .02 Breath Alcohol Detection System are safe and effective as an evidentiary breath test, the ALCO SENSOR IV manufactured by Intoximeters, Inc. which is a DOT/NHTSA approved device (Conforming Products List of Evidentiary Breath Measurement Devices – FR/Vol.69, No.134/July 2004/Notices/42237).

User studies were performed to establish that the user could read and understand the directions provided and properly use the devices (Tables 1 and 2).

Table 1
Comparison to Evidentiary Breath Test (Alco-Sensor IV)

	Evidentiary Breath Test Results			
Breath Alcohol ☑® *.02* Detection System **Result**	**Less than 60%** below the Cutoff (< 0.008%)	**Near Cut-off Negative** (0.008 to 0.020%)	**Near Cut-off Positive** (>0.020 to 0.032%)	**High Positive** (> 0.032%)
Positive	0	1	8	11
Negative	22	3	0	0

Table 2
Comparison to Evidentiary Breath Test (Alco-Sensor IV)

	Evidentiary Breath Test Results			
BreathScan® .02 Breath Alcohol Detection System **Result**	**Less than 60%** below the Cutoff (< 0.008%)	**Near Cut-off Negative** (0.008 to 0.020%)	**Near Cut-off Positive** (>0.020 to 0.032%)	**High Positive** (> 0.032%)
Positive	0	1	8	11
Negative	22	3	0	0

Additionally, the Breath Alcohol ☑® *.02* Detection System and BreathScan® .02 Breath Alcohol Detection System were evaluated and found to meet the guidelines provided in the DOT/NHTSA Model Specifications for Alcohol Screening Devices –(Federal Register/Vol. 59, No. 147, August 2, 1994/Notices/39382).

5.8 Substantial Equivalence

The similarities and differences between the Breath Alcohol ☑® *.02* Detection System and BreathScan® .02 Breath Alcohol Detection System and the Connectables® Alcohol Tester (predicate device) are summarized in Tables 3 and 4.

Table 3

Similarities and Difference Between
Breath Alcohol ☑® *.02* Detection System and CONNECTABLES®

SIMILARITIES		
Parameter	**Device**	**Predicate**
	Breath Alcohol ☑® *.02* Detection System	CONNECTABLES® Alcohol Tester **K052448**
Indications for Use	Detect the presence of alcohol in human breath.	Detect the presence of alcohol in human breath.
Target Populations	Over the Counter	Over the Counter
Display	Red, Green LEDs	Red, Yellow, Green LEDs
Calibration/Accuracy Checks	None required	None required
Result	Qualitative	Semi-Quantitative
Construction	Plastic case with internal circuit board	Plastic case with internal circuit board

DIFFERENCES		
Parameter	**Device**	**Predicate**
Test Sample	Breath Alcohol ☑® .02 Detector charged with human breath	Human Breath
Mouthpiece	None required	Replaceable
Anatomical Site	None	Mouth
Instrument System	Reflectance Measurement	Semiconductor-Oxide Sensor
Measurement Range	Defined limits, <.02% = Green flashing LED (negative) and ≥.02% Red flashing LED (positive)	Upper limit undefined – any concentration greater than .04% will produce red light
Warm Up Time	None	5-15 seconds
Dimensions	2 by 3 3/8 inches	2.1 by 1.64 inches
Weight	75 grams	42 grams
Battery Life	1000 measurements	400 measurements
Power Source	2- CR2032 batteries (built in)	2-AAA alkaline batteries

Table 4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Barbara A. Bagby
Akers Biosciences, Inc.
201 Grove Road
Thorofare, NJ 08086

DEC 18 2006

Re: k062971
Trade/Device Name: Breath Alcohol ✓® .02 Detection System
BreathScan® .02 Breath Alcohol Detection System
Regulation Number: 21 CFR 862.3050
Regulation Name: Breath-alcohol test system
Regulatory Class: Class I, reserved
Product Code: DJZ
Dated: September 28, 2006
Received: September 29, 2006

Dear Ms. Bagby:

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

Indications for Use

510(k) Number (if known): k062971

Device Name: Breath Alcohol ☑® *.02* Detection System
BreathScan® .02 Breath Alcohol Detection System

Indications For Use:

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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)

...n Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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