Traditional 510(k) NOTIFICATION (21 CFR 807.90(e)):
Alco-Breath Tube and CheckPoint® Breath Alcohol Test

510(k) SUMMARY

APR - 6 2011

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: K102225

Submitted By:	AlcoPro, Inc. 2547 Sutherland Avenue Knoxville, TN 37939 USA Telephone: 1-800 227-9890
Company Contact:	Jack Singleton, President
Date Summary Prepared:	7/26/2010
Trade Name:	Alco-Breath Tube; CheckPoint® Breath Alcohol Test
Common Name:	Devices, Breath trapping, alcohol
Regulation Number and Panel:	862.3050 - Toxicology
Classification Product Code:	DJZ
Classification:	Class I
Substantially Equivalent Devices:	K060761 – BreathScan Alcohol Detector

Device Description:

The Alco-Breath Tube is a disposable, one-time use in vitro diagnostic (IVD) device using a length-of-stain method to give estimates of alcohol concentrations. A chemical reaction occurs when the reagent-treated silica gel is exposed to breath alcohol at or greater than the threshold level of the test device. The results are interpreted based on the observation of a color change within a specified period of test time. The color change is proportional to the concentration of alcohol in the breath. The device provides preliminary screening test results and is not intended to be used as evidential results.

The Alco-Breath Tube is intended to detect the presence of alcohol in the breath at concentrations between 0.02 BrAC (Breath Alcohol Concentration) and 0.08 or 0.15 BrAC. The Alco-Breath Tube is intended for screening in medical and therapeutic programs. This product will also give a semi-quantitative estimate of alcohol levels in these ranges. The Alco-Breath Tube is a disposable device designed for one-time use.

Traditional 510(k) NOTIFICATION (21 CFR 807.90(e)):
Alco-Breath Tube and CheckPoint® Breath Alcohol Test

510(k) SUMMARY

The CheckPoint® Breath Alcohol Test is a disposable, one-time use in vitro diagnostic (IVD) device using a color change to indicate the presence of alcohol. A chemical reaction occurs when the reagent-treated silica gel is exposed to breath alcohol at or greater than the threshold level of the test device. The results are interpreted based on the observation of a color change within a specified period of test time. The device provides preliminary screening test results and is not intended to be used as evidential results.

The CheckPoint® Breath Alcohol Test is intended to detect the presence of alcohol in the breath at a concentration of 0.02% or greater. The CheckPoint® comes in four different alcohol levels: 0.02%, 0.04%, 0.05%, and 0.08%. The alcohol level for each device is printed on the label of the device. The CheckPoint® Breath Alcohol Test are a disposable device designed for one-time use and is intended for screening in medical and therapeutic programs.

Intended Use/ Indications for Use:

Device Name: Alco-Breath Tube breath alcohol test

The Alco-Breath Tube is a device to test for alcohol in human breath. It is a disposable device designed for one-time use and is a screening test that gives preliminary results. This device provides a semi-quantitative estimate of alcohol levels in breath. The ABT-08 device gives readings between 0 and 0.08% BAC and the ABT-15 device gives readings between 0 and 0.15% BAC.

Device Name: CheckPoint breath alcohol test

The CheckPoint breath alcohol test is a device to test for alcohol in human breath. It is a disposable device designed for one-time use and is a screening test that gives preliminary results. The test is available at cut-offs of 0.02, 0.04, 0.05, and 0.08% BAC.

Predicate Device:

The predicate device(s) for substantial equivalence in this submission are:

Device Name	BreathScan Alcohol Detector
Company	Akers Biosciences, Inc.
510(k) reference	K060761

Technology Comparison:

Feature	Predicate Device: BreathScan® Alcohol Detector (K060761)	New Device: Alco-Breath Tube	New Device: CheckPoint® Breath Alcohol Test
Intended Use	Detect presence of alcohol in exhaled breath	Same as predicate	Same as predicate

Traditional 510(k) NOTIFICATION (21 CFR 807.90(e)):
Alco-Breath Tube and CheckPoint® Breath Alcohol Test

510(k) SUMMARY

Feature	Predicate Device: BreathScan® Alcohol Detector (K060761)	New Device: Alco-Breath Tube	New Device: CheckPoint® Breath Alcohol Test
Target Population	Over the counter	Same as predicate	Same as predicate
Calibration/ Accuracy Checks	None required	Same as predicate	Same as predicate
Methodology	Chromogenic reaction	Same as predicate	Same as predicate
Anatomical Site	Mouth	Same as predicate	Same as predicate
Test Sample	Exhaled human breath	Same as predicate	Same as predicate
Blowing Time	12 seconds	1 minute	Same as predicate
Test Time	2 minutes	Same as predicate	Same as predicate
Result	Qualitative	Same as predicate; also provides semi-quantitative results	Same as predicate
Interpretive Method	Visual Color Change	Same as predicate	Same as predicate
Measuring Units	BAC %	Same as predicate	Same as predicate
Measurement Range	Separate devices available at different cut-off levels: 0.02%, 0.04%, 0.05%, and 0.08%	Separate devices available at different cut-off levels: 0.04% and 0.08%	Same as predicate
Mouthpiece	None Required	Same as predicate	Same as predicate
Collection Device	None Required	Balloon	Optional volumetric bag

Test Summary:

Performance data – Non-clinical/ Clinical

The conduct of performance evaluation studies is based on the most current National Highway Traffic Safety Administration (NHTSA)/ DOT guidance document. "Highway Safety Programs; Model Specifications for Screening; Devices to Measure Alcohol in Bodily Fluids". (Federal Register: March 31, 2008. Vol 73, No.62, pgs. 16956 – 16960). This is the only national standard available for alcohol screening devices and is the same standard referenced in the 510(k) clearance for the predicate device. Usability tests were conducted to determine if consumers can correctly perform and interpret tests according to the package insert.

Performance Specifications –

The performance characteristics of the Alco-Breath Tube and CheckPoint® Breath Alcohol Test were based on evaluations by the following analytical performance tests:

- Precision/ Reproducibility
- Traceability/ Stability/ Expected Values
- Detection Limit
- Analytical Specificity
  - cigarette smoke
  - temperature
  - vibration
- Comparison Studies

ALCO

Traditional 510(k) NOTIFICATION (21 CFR 807.90(e)):
Alco-Breath Tube and CheckPoint® Breath Alcohol Test

510(k) SUMMARY

Conclusions:

The information in this 510(k) submission demonstrates that the Alco-Breath Tube and CheckPoint® Breath Alcohol Test is safe and effective for its intended use and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Alcopro, Inc.,
c/o Seashore-Tetrachem
Attn:Mr. Perry Rucker
Consultant, Regulatory Affairs, & Compliance
1560 E. Edinger Avenue, Suite B
Santa Ana, CA 92705

APR 6 2011

Re: k102225
Trade Name: Alco-Breath Tube, Checkpoint Breath Alcohol Test
Regulation Number: 21 CFR §862.3050
Regulation Name: Breath Alcohol Test System.
Regulatory Class: Class I, reserved
Product Codes: DJZ
Dated: February 10, 2011
Received: February 15, 2011

Dear Mr. Rucker:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, 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 Form: CheckPoint

510(k) Number (if known): 102225

Device Name: CheckPoint breath alcohol test

Indications for Use:

The CheckPoint breath alcohol test is a device to test for alcohol in human breath. It is a disposable device designed for one-time use and is a screening test that gives preliminary results. The test is available at cut-offs of 0.02, 0.04, 0.05, and 0.08% BAC.

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

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

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K102225

Indications for Use Form: Alco-Breath Tube

510(k) Number (if known): 102225

Device Name: Alco-Breath Tube breath alcohol test

Indications for Use:

The Alco-Breath Tube is a device to test for alcohol in human breath. It is a disposable device designed for one-time use and is a screening test that gives preliminary results. This device provides a semi-quantitative estimate of alcohol levels in breath. The ABT-08 device gives readings between 0 and 0.08% BAC and the ABT-15 device gives readings between 0 and 0.15% BAC.

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 OF NEEDED)

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

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