K082080

510(k) Summary
807.92(c)

APR - 1 2009

SPONSOR **807.92(a)(1)**

Company Name:	Alcotest Quebec
Company Address	3075 Peugot Laval, CA-QC H7L 5C4 Canada
Telephone:	450-666-2500
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Contact Person:	Stephane Maurais

Summary Preparation Date: July 18, 2008

DEVICE NAME **807.92(a)(2)**

Trade Name:	Alco Tube Plus Alcohol Detector
Common/Usual Name:	Breath-alcohol test
Classification Name:	Devices, Breath Trapping, Alcohol
Regulation Number:	CFR21 862.3050
Product Code:	DJZ
Device Class:	Class I

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device:

Company	*Product*	*510(k) #*
Akers Biosciences, Inc.	BreathScan® Alcohol Detector	K060761

DEVICE DESCRIPTION **807.92(a)(4)**

The Alco Tube Plus Alcohol Detector (Tester) is a visual qualitative test for the presence of alcohol in human breath. The tester is constituted of glass tubing containing a reagent of yellow crystals that change color when exposed to alcohol vapors. The other part is an opening to blow into while running the test.

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

The yellow crystals are coated with Potassium dichromate and sulfuric acid. The amount of these indicator chemicals is adjusted according to the selected cutoff of the Tester. A color change is produced when alcohol vapors are oxidized to acetic acid and the indicator chemicals change to chromium sulfate. The majority of crystals change from

yellow to green when alcohol vapors are present at a level equal to or exceeding the cutoff of the Tester.

The Alco Tube Plus is available in two cut-offs (0.05% and 0.08%) The cut-off is printed in the instructions and is expressed as a specific percentage of breath alcohol

DEVICE INTENDED USE **807.92(a)(5)**

The Alco Tube Plus Alcohol Detector is an in vitro medical device to qualitatively detect the presence of alcohol in the human breath. It is a disposable screening device for one-time use. The detector is available in two cut-offs including 0.05 and 0.08 percent breath alcohol. The device 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. Correlation between breath alcohol content and blood alcohol content depends on many variables. Alco Tube Plus is not intended to legally determine blood alcohol presence, level, or inference of intoxication.

COMPARISON OF TECHNICAL CHARACTERISTICS **807.92(a)(6)**

Parameters	**Alco Tube Plus**	**BreathScan®**
510(k) Number	N/A	K060761
Indented Use Statement	Detect the presence of alcohol in the human breath.	Detect the presence of alcohol in the human breath.
Target Population	Over the Counter	Over the Counter
Calibration/Accuracy Checks	None required	None required
Anatomical Site	Mouth	Mouth
Test Sample	Human breath	Human breath
Result	Qualitative	Qualitative
Interpretation	Visual Color Change	Visual Color Change
Measurement Range	Separate devices are pre-calibrated to turn color at different cut-offs: .05% and .08%	Separate devices are pre-calibrated to turn color at different cut-offs: .02%, .04%, .05%, and .08%
Mouthpiece	None Required	None Required
Blowing Time	12 seconds	12 Seconds
Warm-up time	none	None
Size	10 cm	2¾ by 1/3 inches
Weight	6,8 grams	1.9067 grams
Power Requirement	none	None

NONCLINICAL AND CLINICAL TEST **807.92(b)**

SAFETY and EFFECTIVENESS

Testing of the Alco Tube Plus was performed to DOT/NHTSA approved device (Conforming Products List of Evidentiary breath Measurement Devices – FR/Vol. 69,

No. 134/July2004/Notices/42237. User studies were performed to establish that the user could read and understand the directions provided and properly use the device.

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

0.05 tester result (n=200)	Quantitative Results			
	Less than cutoff – 60% (< 0.02%)	Near cutoff negative (0.02 – 0.05%)	Near cutoff positive (> 0.05 – 0.083%)	Greater than cutoff + 60% (> 0.083)
Positive	0	0	70	21
Negative	80	29	0	0

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

0.08 tester result (n=200)	Quantitative Results			
	Less than cutoff – 60% (< 0.02%)	Near cutoff negative (0.02 – 0.05%)	Near cutoff positive (> 0.05 – 0.083%)	Greater than cutoff + 60% (> 0.083)
Positive	0	0	70	21
Negative	80	29	0	0

CONCLUSION **807.92(b)(3)**

After analyzing bench test and user testing data, it is the conclusion of Alcotest Quebec that the Alco Tube Plus Breath Alcohol Detector is as safe and effective as the predicate device. User studies showed that the over the counter purchaser of this device could read and understand the instructions, could properly use the device and obtain results that were comparable to those of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Alcotest Quebec
c/o Mr. E.J. Smith
1468 Harwell Ave
Crofton, MD 21114

APR -1 2009

Re: k082080
Trade/Device Name: Breath Alcohol Detector
Regulation Number: 21 CFR 862.3050
Regulation Name: Breath-Alcohol test system
Regulatory Class: Class I, Reserved
Product Codes: DJZ
Dated: March 25, 2009
Received: March 26, 2009

Dear Mr. Smith:

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use

510(k) Number K082080

Device Name: Alco Tube Plus Alcohol Detector

Indications For Use:

The Alco Tube Plus Alcohol Detector is an *in vitro* medical device to qualitatively detect the presence of alcohol in the human breath. It is a disposable screening device for one-time use. The detector is available in two cut-offs including 0.05 and 0.08 percent breath alcohol. The device 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.

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use ___√___ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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

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