5. 510(k) SUMMARY

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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 K093143.

Submitter's Identification:

ACON Laboratories, Inc.
10125 Mesa Rim Road
San Diego, California 92121

Tel.: 858-875-8019
Fax: 858-875-8099

Date Prepared: October 2009

Contact Person:

Richard Lenart
Regulatory Affairs Manager

Proprietary Name of the Device:

Mission® Breath Alcohol Detector

Common Name:

Breath-alcohol test system

Regulation Section and Classification:

21 CFR § 862.3050	Class I, Breath-alcohol test system

Product Code:

DJZ Devices, Breath trapping, alcohol

Medical Specialty:

Toxicology

Predicate Device:

BreathScan Alcohol Detector
Akers Biosciences Inc., Thorofare, New Jersey, USA 08086.
510(k) Number: K060761

Description:

The Breath Alcohol Detector is a visual semi-quantitative test for the detection of alcohol in the exhaled breath. The Breath Alcohol Detector consists of a plastic tube, two plastic plugs, a blow bag (optional), a tube label and a glass vial encased with reaction crystals. The crystals employ a solid-phase chemistry system based on chemically chromogenic reaction. Alcohol, if present in the exhaled breath, reacts with the chemically coated crystals and produces a color change. This color change is proportional to the concentration of alcohol in the breath, which is an approximation of relative Blood Alcohol Concentration (BAC). The Breath Alcohol Detector is available with or without blow bags in six cut-off levels: 0.02%, 0.04%, 0.05%, 0.06%, 0.08% or 0.10% cut-off levels.

Intended Use:

The Breath Alcohol Detector is for the semi-quantitative rapid detection of the presence of alcohol in the exhaled breath. The Breath Alcohol Detector indicates relative Blood Alcohol Concentration (BAC) at 0.02%, 0.04%, 0.05%, 0.06%, 0.08% or 0.10% cut-off levels.

Technological Characteristics:

Feature	Specifications
Methodology	Chromogenic reaction
Specimen	Exhaled breath
Measurement Range	0.02%, 0.04%, 0.0.05%, 0.06, 0.08% and 0.10%
Measuring Units	BAC %
Reading Time	2 minutes
Reading Stability	5 minutes
Storage Temperature	2-30°C (36-86°F)
Shelf Life	3 years
Dimensions	0.94 x 8.0 cm (0.37 x 3.15 inches)
Weight	2.0 g (0.07 oz)

Comparison to Predicate Devices:

The Mission® Breath Alcohol Detector is substantially equivalent to the Akers Biosciences BreathScan Alcohol Detector.

Feature	Mission® Breath Alcohol Detector	Akers Bioscience BreathScan Alcohol Detector
Similarities		
Intended Use	Detect presence of alcohol in exhaled breath	Same
Target Population	Over the counter	Same
Calibration	None required	Same
Methodology	Chromogenic reaction	Same
Anatomical Site	Mouth	Same
Test Sample	Exhaled breath	Same
Result	Semi-quantitative	Same
Interpretation	Visual color change	Same
Measuring Units	BAC %	Same
Mouthpiece	None required	Same
Blowing Time	12 seconds	Same
Dimensions	0.94 x 8.0 cm (0.37 x 3.15 inches)	Same
Weight	2.0 g (0.07 oz)	Same
Differences		
Measurement Range	Separate devices available at different cut-off levels: 0.02%, 0.04%, 0.05%, 0.06%, 0.08% and 0.10%	Separate devices available at different cut-off levels: 0.02%, 0.04%, 0.05%, and 0.08%
Blow Bag	May be used with or without blow bag	None

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Guidance documents included the "NHTSA/DOT Highway Safety Programs; Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids, (Federal Register/Vol.59, No.147, August 2, 1994/Notices/39382)," and NHTSA/DOT Highway Safety Programs; Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids, (Federal Register/Vol.73, No.62, March 3, 2008/Notices)"

Laboratory Testing:

The performance characteristics of the Mission® Breath Alcohol Detector were evaluated by the following studies: precision, analytical specificity-blank reading, analytical specificity-cigarette smoke, analytical specificity-volatile substances, temperature flexibility, vibration effect, lighting effect and device comparison study.

Discussion of Clinical Tests Performed:

Clinical studies were conducted with laypersons and trained laboratory technicians using the Mission® Breath Alcohol Detector. The study data were presented evaluating the accuracy of the Mission® Breath Alcohol Detector compared to an evidentiary breath test, Alco-Sensor IV, manufactured by Intoximeters Inc. which is a DOT/NHTSA approved device (Conforming Product List of Evidential Breath Alcohol Measurement Devices – FR/Vol 72, No 241/December 2007), per the ACON Clinical Study Protocol for the Breath Alcohol Detector. Study results indicate that non-professional, inexperienced laypersons were able to obtain comparable readings when using the Mission® Breath Alcohol Detector as compared to the results obtained by the trained technicians. In addition, the participating laypersons were questioned and responded as satisfied with the ease of operation by following the Instructions for Use and the overall performance of the Mission® Breath Alcohol Detector.

Conclusion:

The laboratory testing and clinical study results demonstrate that the Mission® Breath Alcohol Detector is safe, accurate and easy-to-use. It also demonstrates that the Mission® Breath Alcohol Detector is substantially equivalent to the Akers Biosciences BreathScan Alcohol Detector, currently sold on the U.S. market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Acon Laboratories, Inc.
c/o Mr. Richard Lenart
Regulatory Affairs Manager
10125 Mesa Rim Road
San Diego, CA 92121

Re: k093143
Trade Name: Mission® Breath Alcohol Detector
Regulation Number: 21 CFR §862.3050
Regulation Name: Breath-Alcohol Test System
Regulatory Class: Class I, reserved
Product Codes: DJZ
Dated: December 11, 2009
Received: December 15, 2009

JAN 28 2010

Dear Mr Lenart:

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 Part 801), 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. 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

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K093143

Device Name: Mission® Breath Alcohol Detector

Indications for Use:

The Breath Alcohol Detector is for the semi-quantitative rapid detection of the presence of alcohol in the exhaled breath. The Breath Alcohol Detector indicates relative Blood Alcohol Concentration (BAC) at 0.02%, 0.04%, 0.05%, 0.06%, 0.08% or 0.10% cut-off levels. 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 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

K093143