5. 510(k) SUMMARY

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 K093879.

AUG - 6 2010

Submitter's Identification:

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

Tel.: 858-875-8019
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Date Prepared: December 2009

Contact Person:

Richard Lenart
Regulatory Affairs Manager

Proprietary Name of the Device:

Mission® Saliva Alcohol Test Strip

Common Name:

Alcohol test system

Regulation Section and Classification:

21 CFR § 862.3040 Alcohol test system

Class II

Product Code:

DIC Alcohol dehydrogenase, specific reagent

Medical Specialty:

Toxicology

Predicate Device:

QED A150 Saliva Alcohol Test
Orasure Technologies Inc., Bethlehem, PA 18018
510(k) Number: K894001

Description:

The Mission Saliva Alcohol Test Strip is a screening test used to semi-quantitatively measure alcohol in human saliva at 0.0%, 0.02%, 0.04%, 0.08%, and 0.30% Blood Alcohol Concentration (BAC). Results are used in the diagnosis of alcohol intoxication. The test is a firm plastic strip with a test pad attached at the tip. The test pad contains chemicals that are highly sensitive to alcohol. Alcohol in saliva reacts with the chemicals to produce a color change on the test pad. The color change depends on the amount of alcohol present. The results are read by comparing the color of the test pad with the color chart. The test gives relative Blood Alcohol Concentration (BAC) from 0.02% to 0.30%.

Intended Use:

The Mission Saliva Alcohol Test Strip is a screening test used to semi-quantitatively measure alcohol in human saliva. The test strip indicates relative Blood Alcohol Concentration at 0.0%, 0.02%, 0.04%, 0.08%, and 0.30% cut-off levels. Results are used in the diagnosis of alcohol intoxication. For in vitro diagnostic use only.

Technological Characteristics:

Feature	Specifications
Methodology	Chromogenic reaction
Specimen	Saliva
Measurement Range	Negative, 0.02%, 0.04%, 0.08% and 0.30%
Measuring Units	BAC %
Reading Time	2 minutes
Reading Stability	3 minutes
Storage Temperature	2-27°C (36-80°F)
Shelf Life	12 months
Dimensions	0.5 x 8.0 cm (0.20 x 3.15 inches)
Weight	0.16 g (0.006 oz)

Comparison to Predicate Devices:

The Mission Saliva Alcohol Test Strip is substantially equivalent to the Orasure Technologies Inc. QED A150 Saliva Alcohol Test.

Feature	Mission Saliva Alcohol Test Strip	Orasure Technologies QED A150 Saliva Alcohol Test
Similarities		
Intended Use	Detect presence of alcohol in saliva	Detect presence of alcohol in saliva
Calibration	None required	Same
Anatomical Site	Mouth	Same
Test Sample	Saliva	Same
Reading Time	2 minutes	Same
Differences		
Measurement Range	Negative, 0.02%, 0.04%, 0.08% and 0.30%	0.01% to 0.145%
Target Population	Over the counter	Professional
Enzyme Used	Alcohol oxidase	Alcohol dehydrogenase
Result	Semi-quantitative	Quantitative
Interpretation	Visual color change using color chart	Visual color change using thermometer-like scale
Measuring Units	BAC %	%BAC and mg/dL

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)," for Lighting Effect Study 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)" for the remaining performance studies.

Laboratory Testing:

The performance characteristics of the Mission Saliva Alcohol Test Strip were evaluated by the following studies: precision, analytical specificity-blank reading, cigarette smoke interference, analytical specificity-volatile substances, temperature flexibility, lighting effect, reading time flexibility, and specimen storage and stability.

Discussion of Clinical Tests Performed:

Clinical studies were conducted with laypersons and trained laboratory technicians using the Mission Saliva Alcohol Test Strip. The study data were presented evaluating the accuracy of the Mission® Saliva Alcohol Test Strip 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. Study results indicate that non-professional, inexperienced laypersons were able to obtain comparable readings when using the Mission Saliva Alcohol Test Strip 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 Saliva Alcohol Test Strip.

Conclusion:

The laboratory testing and clinical study results demonstrate that the Mission Saliva Alcohol Test Strip is safe, accurate and easy-to-use. It also demonstrates that the Mission Saliva Alcohol Test Strip is substantially equivalent to the Orasure Technologies QED A150 Saliva Alcohol Test, currently sold on the U.S. market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Acon Laboratories, Inc.
c/o Mr. Richard Lenart
10125 Mesa Rim Rd.
San Diego, CA 92121
US

AUG 6 2010

Re: k093879
Trade name: Mission Saliva Alcohol Test Strip
Regulation Number: 21 CFR 862.3040
Regulation Name: Alcohol Test System
Regulatory Class: Class II
Product Code: DIC
Dated: June 30, 2010
Received: July 01, 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

K093879

510(k) Number (if known): K093879

AUG - 6 2010

Device Name: Mission® Saliva Alcohol Test Strip

Indications for Use:

The Mission Saliva Alcohol Test Strip is a screening test used to semi-quantitatively measure alcohol in human saliva. The test strip indicates relative Blood Alcohol Concentration at 0.0%, 0.02%, 0.04%, 0.08%, and 0.30% cut-off levels. Results are used in the diagnosis of alcohol intoxication. For in vitro diagnostic use only.

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)

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

510(k) K093879