MAR 2 2 2013

Section 5: 510(k) Summary

Assigned 510(k) number:	k121247
Company:	Chematics Inc. PO Box 293 4519 Highway 13 South North Webster, IN USA 46555 Phone: 574-834-2406 Fax: 574-834-7427
Contact:	Carl Reynolds Phone: 513-265-6257 Email: creynolds@chematics.com
Date Prepared:	March 20, 2012
Proprietary Name:	Alco-Screen®
Classification Name:	Alcohol test system
Classification:	21 CFR 862.3040, Class II, Product Code DIC
Predicate Devices:	K093879 Mission® Saliva Alcohol Test Strip by ACON Laboratories Inc.
Device Description:	ALCO-SCREEN® is a visually read semi-quantitative test for the detection of alcohol in saliva. The test strip indicates the relative Blood Alcohol Concentration (BAC) at 5 different cut-off levels. The device consists of a box of 24 individually packaged single test strips each designed for single use and to be disposable, and instruction for use.
Intended Use:	ALCO-SCREEN® is a semi-quantitative screening test used to estimate the Blood Alcohol Concentration (BAC) using human saliva. The test strip estimates BAC at the 0.00%, 0.02%, 0.04%, 0.08% and 0.3% levels. Results are used in the diagnosis of alcohol use or intoxication. For in vitro diagnostic use.

Technological Comparison to Predicate Device:	Alco-Screen® is similar to the predicate device. Both are OTC screening tests used to semi-quantitatively measure alcohol in human saliva. Additionally, both use chromogenic reaction methodology with alcohol oxidase as the enzyme, and are interpreted by visually comparing color change to a chart. Performance test results confirm that design differences do not pose new issues of safety or effectiveness.
Performance Testing:	The performance characteristics of Alco-Screen® were determined by conducting precision and reproducibility studies, analytical specificity studies, stability studies, and field use studies with an evidentiary device. Results demonstrate that Alco-Screen® performs as intended and meets all established specifications.
Conclusion:	Based upon the design, technology, performance, and intended use, Alco-Screen is substantially equivalent to the predicate device currently marketed under the Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

March 22, 2013

Chematics, Inc.
c/o Carl Reynolds
Regulatory Affairs Specialist
P.O Box 293
4519 Highway 13 South
North Webster, IN 46555

Re: k121247
Trade/Device Name: Alco-Screen Saliva Alcohol Test
Regulation Number: 21 CFR 862.3040
Regulation Name: Alcohol test system
Regulatory Class: Class II
Product Code: DIC
Dated: February 28, 2013
Received: March 12, 2013

Dear Mr. Reynolds:

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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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* Diagnostics and Radiological Health 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,

Carol G. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k121247

Device Name: Alco-Screen® Saliva Alcohol Test

Indications for Use:
ALCO-SCREEN® is a semi-quantitative screening test used to estimate the Blood Alcohol Concentration (BAC) using human saliva. The test strip estimates BAC at the 0.00%, 0.02%, 0.04%, 0.08% and 0.3% levels. Results are used in the diagnosis of alcohol use or intoxication. For in vitro diagnostic use.

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 Diagnostics and Radiological Health (OIR)

Katherine Serrano

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

510(k) k121247