K062545

APR - 9 2007

510(k) Summary

RESOURCE MANAGEMENT INTERNATIONAL, LLC
2330 Ernie Krueger Circle
Waukegan, IL 60087
Telephone: 847-244-4500
Fax: 847-244-4525
March 26, 2007
Contact: John Adams

1. **Identification of the Device**:
   Proprietary-Trade Name: **RMI® LCD Alcohol Tester**
   Classification Name: Device, breath trapping, alcohol, FDA product code DJZ
   Common/Usual Name: Breath-alcohol test system

2. **Equivalent legally marketed device**: Connectables® Alcohol Tester K052448, AlcoMate CA2000, K041334

3. **Indications for Use (intended use)** : Intended to measure alcohol in human breath. Measurements obtained by this device are used in the detection of alcohol intoxication.

4. **Description of the Device**: The RMI® LCD Alcohol Tester is designed to measure deep lung air to test for the presence of alcohol in the blood. The relationship between alcohol in the blood and alcohol in the deep lung breath is well established by Henry's law in ratio of 2100:1. The RMI® LCD Alcohol Tester is an alcohol screening device and uses a blowing time of 3 seconds to capture an accurate deep lung sample. The RMI® LCD Alcohol Tester contains a semiconductor sensor designed to test for the presence of alcohol. The semiconductor material is heated to a specific temperature. The resistance of sensing material changes rapidly according to gas concentration changes, thereby enabling the reading of alcohol concentration by resistance measurement. The device employs a 3 digit LCD display which shows breath alcohol readings from 0.00 to 0.20 BAC (Breath Alcohol Concentration). Readings above 0.20 will display an LCD reading of "HI." The new device is a MODIFICATION of our old device, the Connectables® Alcohol Tester (K052448). We use the same sensor, but instead of three colored LEDs as indicators, the new device has a three digit LCD display of the measured BAC (breath alcohol concentration). Instead of analog comparators, we now employ an 8 bit microprocessor for control and measurement.

5. **Safety and Effectiveness, comparison to predicate device**. The results of bench, and user testing indicates that the new device is as safe and effective as the predicate device. A clinical trial was performed to establish that the user could read and understand the instructions provided, and properly use the device.

6. Substantial Equivalence Chart

Feature	AlcoMate CA2000, K041334	Connectables® Alcohol Tester K052448	RMI LCD Alcohol Tester
INDICATION For USE	Intended to measure alcohol in the human breath. Measurements obtained by this device are used as an aid in the detection of alcohol intoxication.	SAME	SAME
MODE	Breath Alcohol Concentration	SAME	SAME
PRACTITIONER USE	Over the Counter	SAME	SAME
DISPLAY	3 Digit LED	Red, Yellow, and Green LEDs. Representing ranges: BAC of greater than .08% (red) BAC of .04% to .08% (yellow) BAC of less than .04% (green)	3 Digit LCD, with blue LED backlight
POWER SOURCE	9 Volt Alkaline Battery	2-AAA alkaline batteries	2-AAA alkaline batteries
BATTERY LIFE	100-300 tests	400 Tests	300 Tests
Measurement Range	0.00-0.40%	Upper limit undefined - any concentration greater than 0.08% will produce a red light.	0.00-0.20%.. Above 0.2% unit indicates: HI
TYPE OF SENSOR	Semiconductor-Oxide Sensor	SAME	SAME
ANATOMICAL SITE	Mouth	SAME	SAME
Mouthpiece	Replaceable	None required	None required
Warm Up Time	15-60 Seconds	5-15 seconds	5-15 seconds
Blowing Time	5 Seconds	3 Seconds	3 Seconds
Construction	Printed circuit board inside plastic case.	SAME	SAME
SIZE	5" x 2.55"	1.64" x 2.1"	3.5" x 1.25"
WEIGHT	120 grams	42 grams	35 grams

7. Conclusion

After analyzing bench tests, a risk analysis, electrical safety, and user testing data, it is the conclusion of RESOURCE MANAGEMENT INTERNATIONAL, LLC that the RMI® LCD Alcohol Tester is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device. The clinical trial performed 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 provided by a predicate unit administered by a trained observer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Resources Management International, LLC
c/o Mr. Dan Kamm
Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

APR - 9 2007

Re: k062545
Trade/Device Name: RMI® LCD Alcohol Detector
Regulation Number: 21 CFR 862.3050
Regulation Name: Alcohol test system.
Regulatory Class: Class I, reserved
Product Code: DJZ
Dated: March 04, 2007
Received: March 07, 2007

Dear Mr. Kamm:

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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
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

510(k) Number (If Known) K062545

Device Name: RMI® LCD Alcohol Detector

Indications for Use:
Intended to measure alcohol in the human breath. Measurements obtained by this device are 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

(Optional Format 1-2-96) K062545