



Registrar Corp

144 Research Drive, Hampton, Virginia, 23666, USA
P: 757-224-0177 F: 757-224-2045 E: cthornton@registrarcorp.com

510(k) Summary

Section 5. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

5.1 Date: August 3, 2010

K100879
AUG 04 2010

5.2 Submitter:

Official Contact Person: Camille D. Thornton, Registrar Corp
On Behalf of: Contralco
Avenue Mas Faugère BP 23
34150 Gignac
France
+33(0)4 67 91 32 40
Contact: Daniel Calas

5.3 Device:

Trade or Proprietary Name: Contralco Alcohol Breath Tester (0.02, 0.04, 0.05, 0.06, 0.08 and 0.10% BAC)
Common or Usual Name: Breath-alcohol test
Classification Name: Devices, Breath Trapping, Alcohol
Product Code: DJZ
Regulation Number: 862.3050
Device Class: Class I

5.4 Predicate Device:

Contralco Alcohol Breath Tester is equivalent to: Redline disposable Alcohol Breath Tester by Redline Products (Pty) Ltd, (K072953).

5.5 Indication for Use:

The Contralco Alcohol Breath Tester is an in vitro medical device to semi-quantitatively detect the presence of alcohol in the human breath. It is a disposable screening device for one-time use. The detector is available at several detection cut-offs: 0.02, 0.04, 0.05, 0.06, 0.08, and 0.10 relative percent Blood Alcohol Concentration (BAC). 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.

5.6 Description of the Device:

The Contralco Alcohol Breath Tester is a visual qualitative test for alcohol in human breath. The Tester contains chemicals that change color in the presence of alcohol vapors. The Tester is made up of 2 parts: the reagent and the plastic bag. One part contains light yellow crystals that change color when exposed to alcohol vapors. The other part (plastic bag) collects the volume of air necessary for the analysis.

If alcohol is present, the crystals will change from yellow to light green. The number of crystals that change color will depend on the cut-off of the Tester and the amount of alcohol in the breath.

The yellow crystals in the reagent are coated with Chromium VI oxide (CrO_3) and sulfuric acid (H_2SO_4). The amount of these indicator chemicals is adjusted according to the selected cut-off of the tester. A color change is produced when alcohol vapors are oxidized to acetic acid and the indicator chemicals change to chromium sulfate [$\text{Cr}_2(\text{SO}_4)_3$]. The majority of crystals change from yellow to light green when alcohol vapors are present at a level equal to or exceeding the cut-off of the Tester. The Contralco Tester is available in several cut-offs (0.02, 0.04, 0.05, 0.06, 0.08 and 0.10%). The cut-off is printed on the Tester label and is expressed as a specific percentage of breath alcohol.



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5.7 Substantial Equivalence:

Parameter	Contralco Device	Predicate: Redline (K072953)
Indication for use	Detects the presence of alcohol in the human breath	Detects the presence of alcohol in the human breath
Target Populations	Over the Counter	Over the Counter
Calibration/ Accuracy Checks	None required	None required
Anatomical Site	Mouth	Mouth
Test sample	Human breath	Human breath
Collection device	Plastic bag	Plastic bag
Blowing time	12 seconds	12 seconds
Result Interpretation	Extent of color change	Extent of color change
Measurement Range	Separate devices are pre-calibrated to turn color at different cut-offs : 0.02%, 0.04%, 0.05%, 0.06%, 0.08%, 0.10%	Separate devices are pre-calibrated to turn color at different cut-offs : 0.02%, 0.04%, 0.05%, 0.08%, 0.10%
Protection of alcohol breath test against the humidity	The reactant is placed in a glass tube with opercula at both extremities to assure total protection of the reactant against humidity and guarantee an optimal preservation of the test.	At either end of the tube, amorphous silica gel particles act as a protective barrier and are discarded before use.

5.8 Safety and Effectiveness:

A study was conducted to compare Contralco Alcohol Breath Tester with a quantitative comparator device. The purpose of the study was to determine if consumers could correctly perform and interpret the test according to the package insert. The quantitative comparator device is LION, manufactured by LION LABORATORIES LIMITED.

Multiple user studies were performed to establish that the user could read and understand the directions provided and properly use the device.

This study was conducted at the exit of a nightclub. Volunteers blew in balloons, and interpreted the results of the reactant. The volunteers then immediately provided another breath sample, which was analyzed using the quantitative device operated by a trained individual.

59 measures were taken.

The results are presented in the table below:

Contralco 0.05% Tester Result	Quantitative Results			
	Less than 60% the cut-off (<0.02%)	Near Cut-Off Negative (0.02 to 0.05%)	Near Cut-off Positive (≥0.05 to 0.08 %)	More than +60% of cut- off (>0.08%)
Positive	0	0	10	17
Negative	18	13	1	0

The results from the Contralco Alcohol Breath Tester are coherent with the results of the quantitative comparator device (LION). Only one measurement is not coherent with the results of the quantitative comparator. In this case, the Contralco Alcohol Breath Tester is 98% effective.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Contralco
c/o Camille D. Thornton
Registrar Corp Medical Devices
144 Research Drive
Hampton, Virginia 23666

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

Re: k100879
Trade Name: Contralco Breath Alcohol Tester
Regulation Number: 21 CFR 862.3050
Regulation Name: Breath-alcohol Test System
Regulatory Class: Class I, Reserved
Product Codes: DJZ
Dated: July 12, 2010
Received: July 13, 2010

AUG 4 2010

Dear Ms. Thornton:

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).

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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,

A handwritten signature in black ink, appearing to read 'CCH', with a long horizontal flourish extending to the right.

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

Indications for Use

AUG 04 2010

510(k) Number (if known): K100879

Device Name: Contralco Alcohol Breath Tester

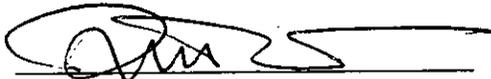
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Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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) K100879