DEC 19 2008

EXHIBIT 2

510(k) Summary for K082086

The Ashley Collection Inc. dba PROTOCOL
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Contact: Robert Goldy, CEO
Date prepared: November 13, 2008

1. Identification of the Device:
   Proprietary-Trade Name: Protocol Alcohol Breath Checker
   Classification Name: Device, breath trapping, alcohol, DJZ
   Common/Usual Name: Breath-alcohol test system

2. Equivalent legally marketed devices K052448, Connectables Pocket Breathalyzer

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

4. Description of the Device: Protocol's alcohol breath checker is designed to measure deep lung air to test for the presence of alcohol in the blood. Protocol's breath checker is an alcohol screening device and uses a blow time of at least 3 seconds to capture an accurate deep lung sample. Protocol's alcohol breathe tester contains an oxide semiconductor sensor designed to test for the presence of alcohol. The oxide 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 provides a semi-quantitative measure of a patient's blood alcohol level using colored LEDs as indicators. The indications are: Red & Yellow: BAC 0.08 or more; Yellow: BAC 0.05 to 0.08; Green: BAC < 0.05. The device also includes a flashlight function and a count-up/count-down timer. The timer can be used for parking meter timing or for timing the wait before performing the alcohol test after consuming alcohol, nominally 20 minutes.

5. Safety and Effectiveness, comparison to predicate device. The results of bench, laboratory 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, as well as perform comparably to an evidentiary type of breath alcohol tester.

6. Substantial Equivalence Chart

Feature	K052448, Connectables Pocket Breathalyzer	Protocol Alcohol Breath Checker
INDICATION OF USE	The Connectables Pocket Breathalyzer is intended to measure alcohol in human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.	This device is intended to measure alcohol in human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication. (SAME)
MODE	Breath Alcohol Concentration	SAME
PRACTITIONER USE	Over the Counter	SAME
Blowing time	3 Seconds	3 Seconds (SAME)
DISPLAY	Three colored LEDs: Red, Yellow, Green.	SAME
Display Interpretation	Red: BAC > 0.08 Yellow: BAC 0.04 to 0.08 Green: BAC < 0.04	Red & Yellow BAC 0.08 or more Yellow: BAC 0.05 to 0.08 Green: BAC < 0.05
POWER SOURCE	2- AAA Alkaline	SAME
BATTERY LIFE	400 Tests	300 Tests
Measurement Range	0.00-0.40% BAC	SAME
Accuracy	+/-0.01%	SAME
TYPE OF SENSOR	Semiconductor-Oxide Sensor	SAME
ANATOMICAL SITE	Mouth	SAME
Warm Up Time	5-15 seconds	SAME
Construction	Plastic case with internal circuit board	SAME
SIZE	1.64" x 2.1"	1.5" x 3"
WEIGHT	42 gm	51 gm.
Flashlight	YES	YES
Timer	NO	Count-up or Count-down

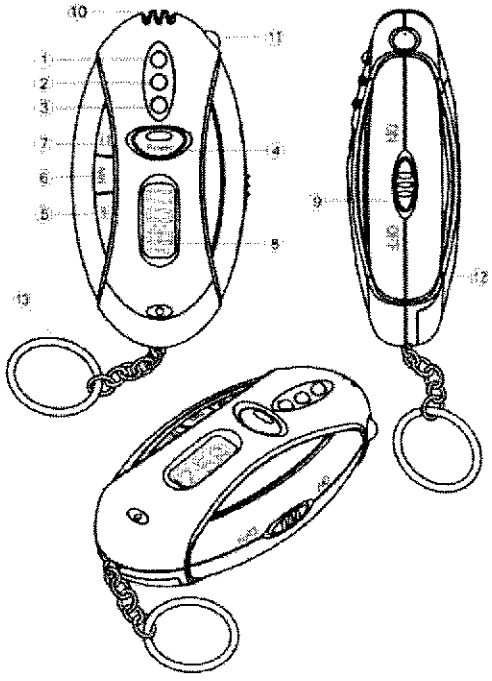
7. Conclusion

After analyzing bench tests, EMC, and user testing data, it is the conclusion of Protocol that the Protocol Alcohol Breathalyzer 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 professional unit administered by a trained observer.

Protocol Breath Alcohol Tester

Intended Use

This device is intended to measure alcohol in the human breath. Measurements obtained by this device are used as an aid in the detection of alcohol intoxication.



(1) Red LED
(2) Yellow LED
(3) Green LED
(4) POWER Button
(5) Hour Button
(6) Minute Button
(7) START/STOP Button
(8) LCD Display for Timer
(9) Light Switch
(10) Sensor Opening
(11) Light
(12) Battery Compartment
(13) Keychain

Before Using

Open the battery lid on the back of the unit. Insert two "AAA" (UM-4) high-quality alkaline batteries. (not included) with correct polarity as indicated. Replace the battery lid. The unit is now ready for use.

Useful Tips

1. WAIT 15 to 20 minutes after drinking alcohol before testing.
2. You must press and hold down the POWER button during the entire test.
3. If left idle far a long time, the Red & Yellow LEDs will light up showing the unit needs more time to warm up. Continue to press the POWER button until the unit shows only the green LED lit.
4. When the batteries are low, the Red and Yellow LEDs may light up during the alcohol test. Replace the batteries at this point.
5. Don't use the light during an alcohol test.
6. See Warnings regarding device replacement.

Using Alcohol Tester

WAIT 15 to 20 minutes after drinking alcohol. Alcohol in your mouth could give you an abnormally high reading.

1. **Press and hold the POWER button until just the green LED is lit. When just the green LED is lit, the unit is ready for testing. Hold the power button continuously during and after the testing.**
2. **Take a deep breath and exhale into the sensor at top of unit for 3 seconds slowly and consistently. The test results will occur immediately. Do NOT touch the top of the unit with your lips.**
3. **Observe which LEDs appear. See the chart below for the LED codes.**
4. **Replace unit after one year. See Warnings**

Wait 15-20 seconds before running the test again

What the LEDs mean:

RED and YELLOW	● ○ ○	**BAC of .08% or greater**	**LEGALLY INTOXICATED.**
YELLOW	○ ○ ○	**BAC of .05% to .08%**	**CAUTION: BORDERLINE INTOXICATED.**
GREEN	○ ○ ●	**BAC of less than .05%**	**LOW or MODERATE LEVEL BUT YOUR DRIVING MIGHT STILL BE IMPAIRED**
No Lights	**Replace the batteries**		

"BAC" means "Blood Alcohol Concentration"

CAUTION: Your driving may be impaired at ANY level of alcohol consumption. This may be true even if only the green light is lit.

DON'T DRINK AND DRIVE!

Warnings

Our testing has shown that this device functions accurately for at least 400 tests. Based on NIAAA studies, (www.alcoholism.about.com) this corresponds to approximately one year of device use for most drinkers. YOU SHOULD REPLACE YOUR DEVICE ONE YEAR AFTER FIRST USE. FAILURE TO DO SO MAY CAUSE YOUR READINGS TO BE INACCURATE. If you are a heavy drinker or a heavy smoker, we strongly recommend replacing the unit sooner.

The Alcohol Tester" does not guarantee 100% accuracy or the same results of the breathalyzers used by law enforcement officials. Test results are guides only and should not be relied upon. Results can be affected by environmental conditions, direct sunlight, excessive heat, submersion in liquids, improper usage, and elapsed time after drinking, amount of food consumption, medication and other drugs consumed. It is strongly advised that no motor vehicle or equipment be used after consuming any amount of alcohol, regardless of the results of the Alcohol Tester. The Alcohol Tester uses a colored LED indicator system (Green, Yellow, and Red) to deliver test results. Results should not be interpreted by individuals who are colorblind or visually impaired.

Specifications

Test Method: Product uses a semi-conductor gas sensor to detect alcohol on breath and converts it to a BAC level.
Preheat time: 5 to 15 seconds (unless the Alcohol Tester was just used)
Battery life: About 200 tests with two "AAA" alkaline batteries
Calibration: Breath alcohol simulator with 0.05 and 0.08 BAC solution, done in factory at time of manufacture
Device life: One year, approximately 400 tests.
Operating temperature: 10 to 40°C
Storage temperature: 0 to 50°C

Other Functions

Light Function

Set the light switch to <ON> position to turn on the light. Do not use the light while using the alcohol tester.

Count-up timer

1. Press the START/STOP button to start the count-up timer when the setting is 0:00
2. Press the START/STOP button again to stop the count-up timer.
3. To reset the count-up timer to 0:00, press the HR and MIN buttons at the same time.

Countdown timer

1. Press HR or MIN buttons to set the countdown HOUR or MINUTE.
2. Press the START/STOP button to start the countdown timer.
3. Press the START/STOP button again to stop the countdown timer.
4. A two second warning signal will be given at the last 10 and 5 minutes.
5. The alarm of the countdown timer lasts 60 seconds. Pressing the HR and MIN buttons at the same time can stop the alarm earlier.
6. To reset the countdown timer to 0:00 press the HR and MIN buttons at the same time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

The Ashley Collection, Inc.
Attn: Mr. Robert Goldy
600 West 57th St., 2nd Floor
New York, NY 10019

DEC 19 2008

Re: k082086
Trade Name: Protocol Alcohol Breath Alcohol Tester
Regulation Number: 21 CFR 862.3050
Regulation Name: Breath-Alcohol Test System
Regulatory Class: Class I, reserved
Product Codes: DJZ
Dated: November 14, 2008
Received: November 17, 2008

Dear Mr. Goldy:

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: **K082086**

Device Name: **Alcohol Breath Tester**

Indications for Use:

This devise is intended to measure alcohol in the human breathe. Measurements obtained by this device are use as an aid in the detection of alcohol intoxication.

Prescription Use: _____ **(Part 21 CFR 801 Subpart D)**	**and/or**	**Over-the-Counter Use (OTC):** _x_____ **(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 Devices,
Evaluation and Safety
510(k) No. K082086