K090766

510(k) Summary

JUL 23 2009

510(k) owner

LifeGuard, a division of Lifeloc Technologies
12441 W. 49th Ave. #4
Wheat Ridge, CO 80033
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Contact Person: Mark Lary, Vice President of Operations

Date Prepared: March 20, 2009

Device Name(s)

Proprietary or trade name: LifeGuard
Alternate proprietary or trade name: BacTrack B90
Common name: Breath Alcohol Test System
Regulation number: 21 CFR 862.3050
Device Classification name: Devices, Breath Trapping, Alcohol
Classification product code: DJZ

Indications for Use

The LifeGuard and BacTrack B90 devices are intended to measure alcohol in human breath. Measurements obtained from these devices are used in the diagnosis of alcohol intoxication.

The LifeGuard and BacTrack B90 devices are intended to be used by the general adult population and by qualified personnel, such as physicians, nurses, and technicians.

The LifeGuard and BacTrack B90 devices are intended to be used by adults (age 21 and over) in measuring alcohol intoxication in themselves or others.

The LifeGuard and BacTrack B90 devices are intended to be used in both home (over-the-counter) and clinical settings.

Predicate Device Summary

The LifeGuard and BacTrack B90 devices are claimed to be substantially equivalent to these legally marketed devices: Drager 6510 (k063443) and AlcoHawk PT-500 (k080848).

Description of Device

The LifeGuard product is a breath alcohol detector designed to sample the patient's deep lung air in order to test for the presence of alcohol in the blood. The sensor used in the LifeGuard is an electrochemical fuel cell sensor. When the patient exhales into the device, after 4 seconds a sample of the breath is pumped into the fuel cell and

generates an electrical current. The amount and duration of the current has a known relationship to the concentration of alcohol in the breath sample. The relationship between the alcohol concentration in the deep lung breath and in the blood is known by Henry's law with a ratio of 2100:1.

The BacTrack B90 has the same intended use, description and performance characteristics as the LifeGuard with a different physical appearance.

Both the LifeGuard and BacTrack B90 products are handheld and are used with a single-use disposable mouthpiece and a replaceable 9 volt battery.

Table 1 - Predicate Device Feature Comparison

Device Trade Name	LifeGuard BacTrack B90	Predicate 1 Drager 6510	Predicate 2 AlcoHawk PT-500
510K number		k063443	k080848
Intended use/Indications for use	Intended to measure alcohol in human breath. Readings from this device are used to determine alcohol intoxication.	Same	Same
Patient Population	General Public (Over the counter use) and clinical settings	General Public (Over the counter use)	General Public (Over the counter use)
Sensor Type	Electrochemical Fuel Cell	Electrochemical Fuel Cell	Electrochemical Fuel Cell
Construction	Plastic case with internal circuit board	Same	Same
Mouthpiece	Single use disposable	Single use disposable	Single use disposable
Power Source	9 volt battery	2 AA batteries or rechargeable NiMH battery	2 AA batteries
Battery Life	300 tests	~1500 tests	~200 tests
Measuring range	.000 to .400 BAC	.000 to .500 BAC	0.000-0.400 BAC
Dimensions	5 1/4" H x 2 1/2" W x 1" D	5 1/2" H x 3 1/8 " W x 1 1/3" D	5" x 2.63" x 1.25"
Weight	140 grams	200 grams	147 grams
Warm up time	None	None	10-20 seconds
Sample time	4 seconds and 1liter of breath	1.2 liters of breath. Volume and time are adjustable.	Default 5 seconds, adjustable from 3-8 seconds
Display	Graphic OLED	Graphic LCD	Graphic LCD
Accuracy	+/- .005 BAC from 0 to .100 BAC. +/- 5% above .100 BAC	reproducibility with an ethanol standard: from 0 to 0.5 mg/l +/- .008 mg/l above .5 mg/l +/-1.7% of measured volume (from 0 to .105 BAC +/-.00168 BAC, above .105 BAC +/- 1.7%)	±0.005 BAC at .050 BAC
Operating temperature	0-50C	-5-50C	10-40C (50-104F)
Calibration interval	1 year	6 months	Every 6-12 months, or monthly calibration may be required if the unit is used daily.

Safety and Effectiveness Comparison to Predicate Device

The results of laboratory bench testing, NRTL safety testing, and user studies indicate that the LifeGuard device is as safe and effective as the predicate device. Verification testing was done to verify the device's hardware and firmware performance met the requirements stated in the device specifications. Safety testing was performed by a Nationally Recognized Test Lab to certify compliance with applicable US and European safety standards for a medical device. A usability study was done to validate that the device met the requirements of the users and that the device labeling was adequate to describe the proper use of the device.

Conclusion

The combination of the LifeGuard design, feature set, verification and validation results, and agency testing reports demonstrate that the LifeGuard breath alcohol tester is a safe, effective product that is substantially equivalent to other FDA cleared alcohol breath testing products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

LifeGuard, a Division of Lifeloc Tech.
c/o Mr. Mark Lary
Vice President of Operations
12441 W. 49th Avenue #4
Wheat Ridge, CO 80033

JUL 23 2009

Re: k090766
Trade Name: LifeGuard / Backtrack B90 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 15, 2009
Received: July 16, 2009

Dear Mr. Lary:

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.
Acting 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): k090766

Device Name: LifeGuard
BacTrack B90

Indications For Use:

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Prescription Use ___X___ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use __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
Device Evaluation and Safety

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