K083801

MAR 19 2009

510(k) Summary
510(k) Number

KHN Solutions LLC
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Contact: Keith Nothacker, President
Date Prepared: December 6, 2008

1. **Identification of the Device:**
   Proprietary-Trade Name: Bactrack® Select Breathalyzer (3 models: S30, S50, S70)
   Classification Name/Product Code: Devices, breath trapping, alcohol, DJZ
   Common/Usual Name: Breath Alcohol Tester

2. **Equivalent legally marketed device**: AL-5000 K061922, SENTECH KOREA CORP.

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**: The BACTRACK® Select Breathalyzer is an alcohol screening device, used for the detection of alcohol in the breath. The BACTRACK® provides a digital result, indicating the approximate BAC (Blood Alcohol Content) of the test subject. The BACTRACK® is powered by two AA batteries (two AAA batteries for model S30) and is very easy to use. The device employs a silicon sensor of the same type commonly used in handheld breathalyzers. The units are factory calibrated but the product should be recalibrated at least every six to twelve months. If the product is used every day, it may need to be recalibrated as frequently as every month.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench, test laboratory, and clinical testing indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart

Feature	AL-5000 K061922 SENTECH KOREA CORP	BACTRACK® Select: S30, S50, S70
INDICATION OF 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.	SAME
MODE	Breath Alcohol Concentration	SAME
PRACTITIONER USE	Over the Counter	SAME
Blowing time	5 Seconds	SAME
DISPLAY	3 Digit LED	S50: Identical to AL-5000 S30: 3 Digit LCD S70: 4 Digit LCD
POWER SOURCE	2 – AA Alkaline	SAME except 2-AAA for Model S30.
BATTERY LIFE	"Over 200 tests"	SAME. 200-300 tests for all 3 models
Measurement Range	0.00% to 0.40%	SAME
Accuracy	± 0.01% BAC at 0.10% BAC	SAME
TYPE OF SENSOR	Semiconductor-Oxide Sensor	SAME
ANATOMICAL SITE	Mouth	SAME
Mouthpiece	Replaceable, polystyrene	SAME as AL-5000
Warm Up Time	15-25 seconds	SAME
DOT	DOT Approved	Meets DOT requirements, approval in process
Construction	Plastic case with internal circuit board	SAME
SIZE	116 x 59 x 27 mm	S50: Identical to AL-5000 S30: 103 x 34 x 25 mm S70: 122 x 58 x 22 mm
WEIGHT	105 g.	S50: Identical to AL-5000 S30: 53/77 g (without, with batteries) S70: 67/115g (without, with batteries)

7. **Conclusion.** After analyzing bench tests, laboratory tests, a risk analysis, EMC, and clinical testing data, it is the conclusion of KHN Solutions that the BACTRACK® Select 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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KHN Solutions, LLC
c/o Daniel Kamm, P.E.
Kamm & Associates
PO Box 7007
Deerfield, IL 60015

Re: k083801
Trade/Device Name: Bactrack® Select Breathalyzer Models S30, S50, and S70
Regulation Number: 21 CFR 862.3050
Regulation Name: Breath-alcohol test system
Regulatory Class: Class I, reserved
Product Code: DJZ
Dated: December 16, 2008
Received: December 22, 2008

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 (301) 594-3084. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

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

Indications for Use

510(k) Number (if known): K083801

Device Name: Bactrack® Select Breathalyzer (3 models- S30, S50, S70)

Indications For Use:
This device is intended to measure alcohol in human breath. Measurements obtained by this device 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)

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K083801