K071069

1 of 2

EXHIBIT 2

510(k) Summary

KHN Solutions LLC
300 Broadway, Suite 26
San Francisco, CA 94133
Phone: 415-693-9756
Fax: 415-358-8030
Email: info@khnsolutions.com

SEP 14 2007

December 20, 2006
Contact: Keith Nothacker, President

1. Identification of the Device:
   Proprietary-Trade Name: BACTRACK™ Breathalyzer Digital Alcohol Detector
   Classification Name: Device, breath trapping, alcohol, DJZ
   Common/Usual Name: Breath-alcohol test system

2. Equivalent legally marketed devices KHN Solutions AlcoMate CA2000™ Digital Alcohol Detector, K041334

3. Indications for Use (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..

4. Description of the Device: The BACTRACK™ Breathalyzer 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 BACTRACK™ Breathalyzer is has been tested and uses a blow time of 5 seconds to capture an accurate deep lung sample. The BACTRACK™ Breathalyzer sensor uses tin dioxide which has n-type conductivity when exposed to the atmosphere. This exposure causes a decrease in the number of electrons effecting absorbed oxygen molecules and thus increases resistance. If a specific gas (reducing gas) is presented, a reaction occurs with the absorbed oxygen which causes an increase in the electrons in the oxide molecules causing a decrease in resistance. This change in resistance can be measured and used to identify a specific gas (such as alcohol) and can be quantified into a % concentration.

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, as well as perform comparably to an evidentiary type of breath alcohol tester.

K071067

2 of 2

6. Substantial Equivalence Chart

Feature	AlcoMate CA2000™ Digital Alcohol Detector, K041334	BACTRACK™ Breathalyzer
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	3 Digit LCD
POWER SOURCE	9 Volt Alkaline Battery or auto cigar lighter (Optional)	2 – AA Alkaline
BATTERY LIFE	300 Tests	SAME
Measurement Range	.00-.40%	SAME
Accuracy	+/-0.01%	SAME
TYPE OF SENSOR	Semiconductor-Oxide Sensor	Semiconductor-Oxide Sensor
ANATOMICAL SITE	Mouth	SAME
Mouthpiece	Replaceable	No mouthpiece
Warm Up Time	20 seconds	10 Seconds
DOT	DOT Approved	Meets DOT requirements
Construction	Plastic case with internal circuit board	SAME
SIZE	5" x 3 ¼" x 1.2"	4.25" x 1.63" x 0.81" (10.8 x 4.1 x 2.1 cm)
WEIGHT	200 grams.	1.4 oz (39.7 grams)

7. Conclusion

After analyzing bench tests, a risk analysis, electrical safety, EMC, and user testing data, it is the conclusion of KHN Solutions that the BACTRACK™ 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

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

SEP 14 2007

Re: k071067
Trade Name: BACKTRACK™ Digital Alcohol Detector
Regulation Number: 21 CFR §862.3050
Regulation Name: Breath alcohol test system
Regulatory Class: Class I (reserved)
Product Code: DJZ
Dated: August 13, 2007
Received: August 16, 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) K071067

Device Name: BACTRACK™ Digital Alcohol Detector

Indications for 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.

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)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety