EXHIBIT 2

510(k) Summary for K080848

JUL 2 5 2008

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Date prepared: July 18, 2008
Contact: Brian C. Eddy, CEO

1. Identification of the Device:
   Proprietary-Trade Name: AlcoHAWK® PT500 Digital Alcohol Detector
   Classification Name: Device, breath trapping, alcohol, DJZ
   Common/Usual Name: Breath-alcohol test system

2. Equivalent legally marketed devices K043188 AlcoHAWK® Precision Alcohol Detector, Q3 Innovations LLC

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 AlcoHAWK® PT500 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 AlcoHAWK® PT500 has been tested and uses a blow time of 5 seconds to capture an accurate deep lung sample. The AlcoHAWK® PT500 sensor uses a fuel cell type of detector similar to one found on professional units. It is handheld and uses two AA alkaline batteries as a power source. The mouthpiece is replaceable Plexiglas plastic.

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	**K043188 AlcoHAWK® Precision**	**AlcoHAWK® PT500**
INDICATION OF USE	The AlcoHAWK® Precision ™ Digital Alcohol Detector 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	5 Seconds	5 seconds (SAME)
DISPLAY	4 Digit LED	4 Digit LCD (with temperature display)
POWER SOURCE	9 Volt Alkaline Battery or auto cigar lighter (Optional)	2 – AA Alkaline
BATTERY LIFE	100-200 Tests	200 Tests
Measurement Range	.00-.40%	SAME
Accuracy	+/-0.01%	SAME
TYPE OF SENSOR	Semiconductor-Oxide Sensor	Fuel Cell Sensor (similar to evidentiary device.)
ANATOMICAL SITE	Mouth	SAME
Mouthpiece	Replaceable	SAME
Warm Up Time	15-60 seconds	10 Seconds
DOT	DOT Approved	DOT Approved (SAME)
Construction	Plastic case with internal circuit board	SAME
SIZE	4.25" x 2.75"	5 in x 2.63 in x 1.25 in
WEIGHT	130 grams.	3.6 oz (102 g) without batteries, 5.2 oz (147 g) with batteries

7. Conclusion

After analyzing bench tests, a risk analysis, EMC, and user testing data, it is the conclusion of Q3 Innovations, LLC that the AlcoHAWK® PT500 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

Q3 Innovations, LLC
Kamm & Associates
c/o Mr. Daniel Kamm
Principal Consultant
P.O. Box 7007
Deerfield, IL 60015

JUL 25 2008

Re: k080848

Trade/Device Name: AlcoHAWK® PT500 Digital Alcohol Detector
Regulation Number: 21 CFR 862.3050
Regulation Name: Breath-alcohol test system.
Regulatory Class: Class I, Reserved
Product Codes: DJZ
Dated: July 2, 2008
Received: July 8, 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 (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) K080848

Device Name: AlcoHAWK® PT500 Digital Alcohol Detector

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)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K080848