K091714

510(k) Summary

NOV 18 2009

This summary of 5 10(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.)

Prepared: May 22, 2009

Revised: Sep 9, 2009

1.1 Type of Submission: **Traditional**

1.2 Submitter: Skyfine Inc. Limited

Address: Flat A, 10/F., Block A, Tung Chun Industrial Building, 9-11 Cheung Wing Road, Kwai Chung, N.T., HONG KONG

Phone: (852) 6827-6600

Fax: (852) 2448-8918

Contact: Jason Chiang, President

Establishment Registration Number: 3007776657

1.3 Identification of the Device:

Proprietary/Trade name: AlcoDigital Breathalyzer, Model AT576, AT577, AT578, AT579

Common Name: Breath Alcohol Test System

Classification Name: **Devices, Breath Trapping, Alcohol**

Device Classification: **I**

Regulation Number: **862.3050**

Panel: **Toxicology**

Product Code: **DJZ**

1.4 Identification of the Predicate Device:

Predicate Device Name:

AlcoHAWK PT500 Digital Alcohol Detector

Manufacturer:

Q3 INNOVATIONS LLC

510(k) Number or Clearance Information:

K080848

1.5 Intended Use and Indications for Use of the subject device.

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

1.6 Device Description

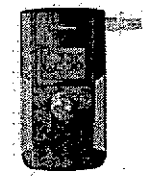
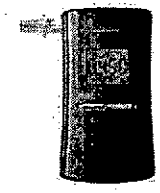
The AlcoDigital Breathalyzer AT576, AT577, AT578, AT579 are designed to measure deep lung air to determine the level of alcohol in the blood. The relationship between alcohol in the blood and in the deep lung breath is well established by Henry's law in ratio of 2100:1. The alcohol sensor is electrochemical fuel cell type, and the unit has been designed to blow 6 seconds to get the sample of alcohol, the sensor generates an output by electronic voltage, which is proportional to the concentration of alcohol in the blood. The unit is powered by 1 pcs 9V battery or DC12V input.

1.7 Safety and Effectiveness

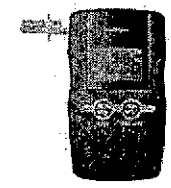
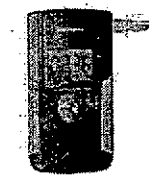
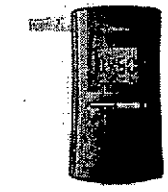
The result of bench and user testing indicates that the new device is as safe and effective as the predicate device. A clinical trial was performed to establish that the user could read and understand the instructions provided, and properly use the device.

1.8 Substantial Equivalence Determination

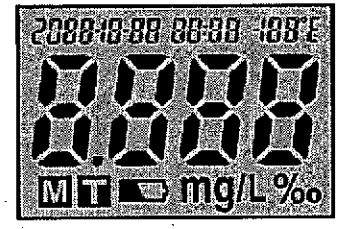
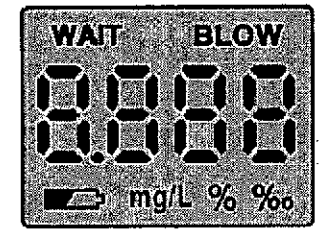
Similarity

Feature	AlcoDigital Breathalyzer AT576	AlcoDigital Breathalyzer AT577	AlcoDigital Breathalyzer AT578	AlcoDigital Breathalyzer AT579
Shape				
Construction	Plastic case with internal circuit board	Same		
Type of Sensor	Fuel Cell Sensor	Same		
Accuracy	±0.005% at 0.05%	Same		
Blowing time	6 seconds	Same		
Blowing flow	10L/min	Same		
Warm up Time	15 seconds	Same		
Testing Time	10 seconds	Same		
Repeat test	less than 60 seconds	Same		
Audible sound alarm if above 0.05%BAC	Yes	Same		
Show "HI" if above the display range	Yes	Same		
Anatomical Site	Mouth	Same		
Mouthpiece	Replaceable	Same		
Power supply	9V battery or DC 12V	Same		
Battery for standard testing	about 500 times	Same		
Low battery indication and auto power off function	Yes	Same		

Similarity

Feature	AlcoDigital Breathalyzer AT576	AlcoDigital Breathalyzer AT577	AlcoDigital Breathalyzer AT578	AlcoDigital Breathalyzer AT579
Shape				
Operation	10°C ~ 40°C	Same		
Store:	-10°C ~ 60°C	Same		
Recalibration interval	12 months	Same		
Blowing pressure and interrupt detection	Yes	Same		
Size	115x60x23mm	Same		
Display range	0.000-0.200%BAC	Same		

Differences

4 digits display with status		
Temperature/Date/Time display	YES	NO
Print /Download	YES	NO
Memory	1000 records	5 records
Buttons	3 buttons: Test, Set Up, Print	2 buttons:Test, Memory
Weight	110g	100g

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

NOV 18 2009

Skyfine Inc. Ltd.
c/o Michael Lee
Acmebiotechs Co. Ltd.
No.45, Minsheng Rd., Danshui Town (Innovation and Incubation Center
of Mackey Memorial Hospital)
Taipei County, TW 251

Re: k091714
Trade Name: Skyfine Inc. AlcoDigital Breathalyzer Models AT576, AT577, AT578, AT579
Regulation Number: 21 CFR §862.3050
Regulation Name: Breath-Alcohol Test System
Regulatory Class: Class I, reserved
Product Codes: DJZ
Dated: October 30, 2009
Received: November 5, 2009

Dear Mr Lee.:

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

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.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K091714

Device Name: AlcoDigital Breathalyzer, Model AT576, AT577, AT578, AT579

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.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use _____ OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K091714