DEC 9 2005

SECTION II
510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

51O{k) Number: Designed K#: 052208

Submitter:

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Contact Person:

Rodrigo Berlie
New Product Development Director
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Preparation Date:

Nov. 10, 2005

Device Information:

Device Classification Name: Quantitative of Blood glucose by using Electrochemical biosensor.
Common/Usual Name: Blood Glucose Monitoring System.
Proprietary Name: Glucose Pilot Glucose Monitoring System.
Regulation Number: 21 CFR§862.1345, Glucose test system.
21 CFR§862.1660, Quantity Control Material
Regulatory Name: Glucose Test System
Product Code: NBW, CGA, JJX
Regulatory Class: Class II

Predicate Devices:

Glucose Pilot Glucose Monitoring System is substantially equivalent to Ultra One Touch Glucose monitoring system of Life Scan. Cleared by FDA (K024194).

Device Description:

The Glucose Pilot Glucose monitoring System consists of a hand-held blood glucose meter, test strips, lancets, Lance device, storage case, and two levels of control solutions. Each lot of test strips has a lot - specific calibration information and the meter reads automatically.
The meter is turned on by inserting the strip, the user supplies the capillary blood or control solution to the strip and the meter makes an audible tone and starts the assay, which completes in five seconds. The meter's software converts the results read off the test strip into a plasma glucose concentration and displays the value on the meter's LCD screen. The sponsor has provided instructions and illustrations explaining that the blood drop will be pulled into the strip sample entry by capillary action. Results are stored in the meter's memory for tracking purposes.

Intended Use:

The Glucose Pilot Blood Glucose Monitoring system is intended for in vitro diagnostic use. The system is intended to be used for the quantitative measurement of capillary whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Comparison to Predicate Device(s):

Glucose Pilot Glucose Monitoring System is substantially equivalent to cleared by FDA, e.g., Ultra One Touch Glucose Monitoring System (024194).

CHARACTERISTICS	NEW DEVICE: *GlucosePilot* BLOOD GLUCOSE MONITORING SYSTEM	PREDICATE: ONETOUCH™ ULTRA GLUCOSE MONITORING SYSTEM
Premarket Notification	K052208	K024194
Manufacturer	New Bay Bioresearch, Co. Ltd.	LifeScan, Inc (U.S.A.)
Type of Meter	Biosensor (Electrode)	Biosensor (Electrode)
Glucose Measurement Technology (Test Strip)	*Glucose pilot* Test Strip	ONETOUCH™ Ultra Test Strip
Intended Use	To quantitatively measure glucose in fresh capillary whole blood.	To quantitatively measure glucose in fresh capillary whole blood.
Sample Source	Capillary whole blood	Capillary whole blood
Sample Application	Blood sample is placed directly to the test strip after finger is lanced.	Blood sample is placed directly to the test strip after finger is

		lanced.
Hematocrit Range	30 – 55%	30 – 55%
Control Solution(s)	*Glucose pilot* Control Solution	ONETOUCH™ Ultra Control Solution
Operating Temperature Range	10°-40°C (50°-104°F)	6°-44°C(43°-111°F)
Operating Humidity Range	25-90% Relative Humidity	10 – 90% Relative Humidity
Dimensions	3.2" (L) x 2.3" (W) x 0.8"(H)	3.12" x 2.25" x 0.85"
Weight	2.5 ounces (72g) including 2 batteries	1.5 ounces(43g) with battery
Display	Liquid Crystal Display (LCD)	Liquid Crystal Display (LCD)
Results Presentation	mg/dL or mmol/L	mg/dL or mmol/L
Memory Capabilities	Stores 350 of the most recent blood test results. Results of the test solution are not stored in the memory.	150 blood glucose and control solution tests
Test Start	Automatic	Automatic
Test Time	5 seconds	5 seconds
Power Source	Two replaceable AAA size batteries	One replaceable 3.0v lithium battery
Battery Life	Approximately 1000 glucose tests.	1000 tests
Measurement Range	20-600 mg/dL (1.1 to 33.3 mmol/L. Lower results are displayed as "LO". Higher results are displayed as "HI".	20 – 600 mg/dL (1.1 to 33.3 mmol/L
Qualified Test Strip	*Glucose pilot* Test Strip	ONETOUCH™Ultra Test Strip
Sample Volume	Minimum of 1 micro liter	Minimum of 1 micro liter

Summary:

The information provided in this pre-market notification demonstrates that Glucose Pilot Monitoring System is substantially equivalent to Ultra One Touch Blood Glucose Monitoring System Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available and analytical predicate devices. The information supplied in this pre-market notification provides reasonable assurance that the Glucose Pilot Glucose Monitoring System is safe and effective for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 9 2005

Tianjin New Bay Bioresearch Co., Ltd.
c/o Mr. Rodrigo Berlie
New Product Development Director
Aviara Biotech, LLC
3108 Avenida Olmeda
Carlsbad, CA 92009

Re: k052208
Trade/Device Name: Glucose Pilot Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, JJX,
Dated: October 27, 2005
Received: November 9, 2005

Dear Mr. Berlie,

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) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
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 STATEMENT

510(k) Number: K052208

Device name: Glucose Pilot Blood Glucose Monitoring System

Indications for Use:

The Glucose Pilot Blood Glucose monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from a finger stick, for the lay-user. It is also intended for the professional use, which include fresh capillary whole blood. It is intended for use outside the body (in vitro diagnostic use) by diabetics at home and clinical setting as an aid to monitor the effectiveness of diabetes control.

Prescription Use ___X___ (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
510(k): K052208