K062829

510(k) SUMMARY

1. DATE PREPARED

September 18, 2006

OCT 1 0 2006

2. SPONSOR INFORMATION

Address

TYSON BIORESEARCH, INC.
5 F., # 22, KE TUNG RD., SCIENCE BASED INDUSTRIAL PARK
CHUN-NAN, MIAO-LI COUNTY, CHINA (TAIWAN) 350

Contact Person: WEN-HAI TSAI

PHONE: 886-37-585988
FACSIMILE: 886-37-585996

3. NAME OF DEVICE:

Trade Name:	DIACHEX Blood Glucose Monitoring System
Common Names/Descriptions:	Blood Glucose Monitoring System
Classification Names:	Glucose test system, product code 75CGA and "System, test, blood glucose, over the counter", product code 75NBW, 21 CFR 862.1345

4. DEVICE DESCRIPTION:

The DIACHEX Blood Glucose Monitoring System designed by Tyson Bioresearch Inc., an amperometric biosensor, are adopted for its ease of use, its ability to process accurate results utilizing only a small volume of blood, and its quick response time. DIACHEX device provides a convenient and safe monitoring system for diabetes health care professionals, hospitals and most importantly, people with diabetes.

The DIACHEX Blood Glucose Test Strips are used with the DIACHEX Blood Glucose Meter to quantitatively measure glucose in capillary whole blood obtained from the fingertip. When the edge of the DIACHEX Test Strip is touched to a drop of blood, the test strip draws the blood into the sample chamber and the glucose reading is displayed

on the meter after 10 seconds. The test measures glucose from 20 mg/dL (1.1mmol/L) to 600 mg/dL (33.3 mmol/L). The DIACHEX Test Strip is calibrated to display the equivalent of plasma glucose values to allow the comparison of results with laboratory methods.

5. INTENDED USE:

The DIACHEX Blood Glucose Test Strips are used with the DIACHEX Blood Glucose Meter for quantitatively measuring glucose (sugar) in fresh capillary whole blood obtained from the fingertip. The DIACHEX Test Strips are for testing outside the body (*in vitro* diagnostic use). The DIACHEX Blood Glucose Monitoring System is intended for use in the home and in professional settings to monitor blood glucose levels.

6. TEST PRINCIPLE

The test principle is based on electrochemical biosensor technology using glucose oxidase. Glucose is oxidized to gluconic acid and electrons are produced from the reaction. The electrons are then trapped by a chemical mediator, potassium ferricyanide. Once the enzymatic reaction is complete, a potential is provided by the meter for a further electrochemical reaction in order to generate a current from the release of trapped electrons. This current is then measured and correlated to the glucose concentration in the whole-blood sample. The DIACHEX Test Strip is calibrated to display the equivalent of plasma glucose values to allow easy comparison of results with laboratory methods.

7. PREDICATE DEVICE:

Predicate device name(s): EZ Smart - 168 Blood Glucose Monitoring System

Predicate 510(k) number(s): k052818

Comparison with predicate:

The Tyson Bioresearch Inc. DIACHEX Blood Glucose Monitoring System in this submission is equivalent to the Tyson Bioresearch Inc. EZ Smart-168 Blood Glucose Monitoring System previously cleared under (k052818). DIACHEX Blood Glucose Monitoring System is an amendment to the EZ Smart-168 Blood Glucose Monitoring System (K052818). This amendment addresses only small changes on the meter size, appearance, memory capacity, date, time and 14days average testing result. All main internal electronic components and meter functions remain as same as the EZ Smart-168

Blood Glucose Meter. DIACHEX Test Strip also identical to the EZ Smart-168 Test Strip, only the size changed for more convenient use. Fundamental scientific technology of the DIACHEX device has not changed.

Substantial Equivalence Comparison:

The Tyson Bioresearch Inc. DIACHEX Blood Glucose Monitoring System in this submission is equivalent to the Tyson Bioresearch Inc. EZ Smart-168 Blood Glucose Monitoring System previously cleared under (k052818). The table below lists the similarities and differences between the Predicate and Proposed device.

Similarities:

Item	Predicate Device EZ Smart-168 (K052818)	Proposed Device DIACHEX
Intend Use	The EZ Smart-168 Blood Glucose Test Strips are used with the EZ Smart-168 Blood Glucose Meter to measure glucose (sugar) in capillary whole blood from fingertip. The EZ Smart-168 Test Strips are for testing outside the body (in vitro diagnostic use). The EZ Smart-168 Blood Glucose Monitoring System provides a convenient and safe monitoring system for diabetes health care professionals, hospitals and most importantly people with diabetes.	The DIACHEX Blood Glucose Test Strips are used with the DIACHEX Blood Glucose Meter to measure glucose (sugar) in capillary whole blood from fingertip. The DIACHEX Test Strips are for testing outside the body (in vitro diagnostic use). The DIACHEX Blood Glucose Monitoring System provides a convenient and safe monitoring system for diabetes health care professionals, hospitals and most importantly people with diabetes.
Test Principle	Electrochemical biosensor with glucose oxidase.	Electrochemical biosensor with glucose oxidase.
Test Strips	EZ Smart-168 Test Strip	DIACHEX Test Strip
Specimen Type	Capillary whole blood from fingertip	Same
Sample Volume	Around 1.5 uL	Same
Measuring Time	10 sec	Same
Detecting Range	20 ~ 600 mg/dL	Same
HCT Range	35 ~55 %	Same
Operating Temperature	10 to 40 ℃ (50-104℉)	Same

Item	Predicate Device EZ Smart-168 (K052818)	Proposed Device DIACHEX
Strip Storage Temperature	4 to 30 ℃ (40-86˚F)	Same
Battery Power	One 3 V Lithium CR 2032 battery	Same
Meter Coding	Glucode Chip	Same

Differences:

Item	Predicate Device EZ Smart-168 (K052818)	Proposed Device DIACHEX
Test Strips size	33.5 x 5 (mm)	33.5 x 7 (mm)
Average result	Only 28 tests average	14-Day Average
Memory capacity	28 Test Results	300 Test Results
Button Design	one button	Two buttons
PCB Size	72 x 42 (mm)	92 x 44 (mm)
Meter Dimension	76 x 47 x 16 (mm)	102 x 52 x 17 (mm)
Meter Weight	44 grams	55 grams
LCD Display	40 x 21.5 (mm)	37.5 x 34 (mm)

8. PERFORMANCE CHARACTERISTIC SUMMARY

Based on the above information, we know the subject device, DIACHEX Blood Glucose Monitoring System, and the predicate device have the same functioning principle and using the same technologies. The detection ranges for both devices are similar. HCT ranges are the same. The strip storage environments and the operating temperature are similar.

The differences between DIACHEX from EZ Smart-168 Blood Glucose Monitoring System are meter dimension, weight, memory capacity, 14 days average result, date and time display, all internal electrical architectures and main electronic components as well as product functions and features remain unchanged. DIACHEX Test Strip is also identical to the EZ Smart-168 Blood Glucose Monitoring System, only the size changed for more convenient use. No physical changes of EZ Smart-168 Test Strips were made.

As we can see, the differences are due to the feature design aspects for more convenience

use of the DIACHEX Blood Glucose Monitoring System, not relating to the safety or effectiveness aspects. Fundamental scientific technology of the DIACHEX device has not changed. DIACHEX Blood Glucose Monitoring System is substantially equivalent to the originally cleared EZ Smart-168 Blood Glucose Monitoring System (K052818).

An evaluation of the DIACHEX Blood Glucose Monitoring System was conducted under various conditions including temperature effects, hematocrit levels, sensitivity and linearity. The results of the evaluation demonstrate that the DIACHEX Blood Glucose Monitoring System is equivalent in performance to the predicate device and suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 10 2006

Mr. Wen-Hai Tsai
Tyson Bioresearch, Inc.
5F., #22, Ke Tung Rd., Science Based Industrial Park
Chun-Nan, Miao-Li County, China (Taiwan) 350

Re: k062829
Trade/Device Name: DIACHEX Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: September 19, 2006
Received: September 20, 2006

Dear Mr. Tsai:

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

510(k) Number: K062829

Device Name: DIACHEX Blood Glucose Monitoring System

Indications For Use:

The DIACHEX Blood Glucose Test Strips are used with the DIACHEX Blood Glucose Meter for quantitatively measuring glucose (sugar) in fresh capillary whole blood obtained from the fingertip. The DIACHEX Strips are for testing outside the body (*in vitro* diagnostic use). The DIACHEX Blood Glucose Monitoring System is intended for use in the home and in professional settings to monitor blood glucose levels for better glucose control among diabetics.

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K062829

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)