

K 123087

510(k) SUMMARY

JUN 18 2013

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

1. Date prepared

May 8, 2013

2. Sponsor information

Tyson Bioresearch, Inc.

5 F., # 22, Ke E. Road III., science based industrial park
Chun-Nan, Miao-Li county, Taiwan 350

Correspondent:

WEN-HAI TSAI

Phone: 886-37-585988 EXT 720

Facsimile: 886-37-585996

3. Device name and classification

Device Name:

TysonBio AC500 Blood Glucose Monitoring System

TysonBio AC800 Blood Glucose Monitoring System

TysonBio AC500 Pro Blood Glucose Monitoring System

TysonBio AC800 Pro Blood Glucose Monitoring System

TysonBio AC500/AC800 Control Solution

TysonBio AC500 Test Strip

TysonBio AC800 Test Strip

TysonBio AC500 Pro Test Strip

TysonBio AC800 Pro Test Strip

Common Names:

Blood Glucose Monitoring System

Classification:

Classification Regulation: 21 CFR 862.1345 and 21CFR 862.1660

Classification: Class II (Glucose Test System)

Class I (Quality control material)

Product Code:

NBW- System, Test, Blood Glucose, Over-the-counter

CGA - Glucose Oxidase, Glucose

JJX - Single (specified) analyte controls (assayed and unassayed)

Panel - Clinical Chemistry and Toxicology

4. Device description

The TysonBio AC500/AC800 Blood Glucose Monitoring System consists of three main products: the meter, test strip, and control solutions. These products have been designed, tested, and proven to work together as a system accurate blood glucose test results. Use only TysonBio AC500/AC800 Test Strips and TysonBio AC500/AC800 Control Solution with the TysonBio AC500/AC800 Blood Glucose Monitoring System.

The TysonBio AC500 Pro/AC800 Pro Blood Glucose Monitoring System consists of three main products: the meter, test strip, and control solutions. These products have been designed, tested, and proven to work together as a system accurate blood glucose test results. Use only TysonBio AC500 Pro/AC800 Pro Test Strips and TysonBio AC500/AC800 Control Solution with the TysonBio AC500 Pro/AC800 Pro Blood Glucose Monitoring System.

The TysonBio AC500/AC800/AC500 Pro/AC800 Pro Blood Glucose Monitoring System consists of:

- a. TysonBio AC500/AC800/AC500 Pro/AC800 Pro Blood Glucose Meter
- b. TysonBio AC500/AC800/AC500 Pro/AC800 Pro Test Strips
- c. TysonBio AC500/AC800 Control Solution

5. Intended use

TysonBio AC500 Blood Glucose Monitoring System :

The TysonBio AC500 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The TysonBio AC500 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The TysonBio AC500 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The TysonBio AC500 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The TysonBio AC500 Test Strips are for use with the TysonBio AC500 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

The TysonBio AC500/AC800 Control Solutions is for use on the TysonBio AC500 Blood Glucose Monitoring Systems to check that the meter and test strips are working together properly and providing accurate results.

TysonBio AC800 Blood Glucose Monitoring System :

The TysonBio AC800 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The TysonBio AC800 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The TysonBio AC800 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The TysonBio AC800 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly). The TysonBio AC800 contains a voice function but this function is not intended for users with impaired vision.

The TysonBio AC800 Test Strips are for use with the TysonBio AC800 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

The TysonBio AC500/AC800 Control Solutions is for use on the TysonBio AC800 Blood Glucose Monitoring Systems to check that the meter and test strips are working together properly and providing accurate results.

TysonBio AC500 Pro Blood Glucose Monitoring System :

The TysonBio AC500 Pro Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, or forearm. The TysonBio AC500 Pro Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with single-use lancing devices.

The TysonBio AC500 Pro Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The TysonBio AC500 Pro Blood Glucose Test Strips are for use with the TysonBio AC500 Pro Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

The TysonBio AC500/AC800 Control Solutions is for use on the TysonBio AC500 Pro Blood Glucose Monitoring Systems to check that the meter and test strips are working together properly and providing accurate results.

TysonBio AC800 Pro Blood Glucose Monitoring System :

The TysonBio AC800 Pro Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, or forearm. The TysonBio AC800 Pro Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the

effectiveness of diabetes control program. This system should only be used with single-use lancing devices.

The TysonBio AC800 Pro Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly). The TysonBio AC800 Pro contains a voice function but this function is not intended for users with impaired vision.

The TysonBio AC800 Pro Blood Glucose Test Strips are for use with the TysonBio AC800 Pro Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

The TysonBio AC500/AC800 Control Solutions is for use on the TysonBio AC800 Pro Blood Glucose Monitoring Systems to check that the meter and test strips are working together properly and providing accurate results.

6. Test principle

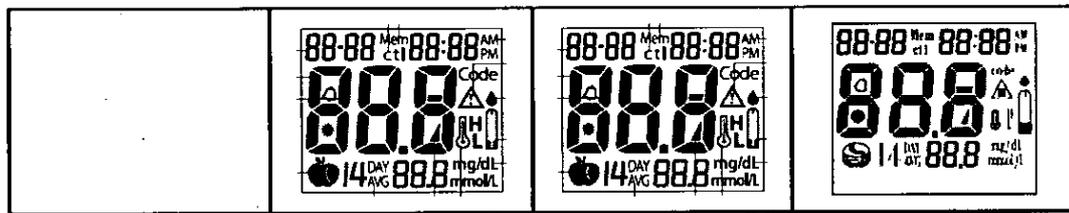
The test principle is based on electrochemical biosensor technology using glucose oxidase. There has been no change to the fundamental scientific technology.

7. Predicate device

TysonBio AC100 Blood Glucose Monitoring System (K101543)

Difference:

Item	Proposed Device		Predicate Device
	TysonBio AC500	TysonBio AC800	TysonBio AC100
Meter appearance			
Backlight	NA	Selectable backlight on/off by user	NA
Voice guidance	NA	Selectable on/off voice guidance	IDENTICAL
Hematocrit range	20-60%	20~60%	35-55%
Meal flag	Apple	Apple	Hamburger



Similarities:

Item	Proposed Device		Predicate Device
	TysonBio AC500	TysonBio AC800	TysonBio AC100
Test principle	Electrochemical biosensor with glucose oxidase.	IDENTICAL	IDENTICAL
Blood sample	Fingertip, palm and forearm	IDENTICAL	IDENTICAL
Sample volume	0.5uL	IDENTICAL	IDENTICAL
Test time	5 seconds	IDENTICAL	IDENTICAL
Detecting range	20 ~ 600 mg/dL	IDENTICAL	IDENTICAL
Unit of measurement	mg/dL or mmol/L	IDENTICAL	IDENTICAL
Coding	Auto coding by inserting the test strip	IDENTICAL	IDENTICAL
Operating temperature	10 to 40 °C (50-104 °F)	IDENTICAL	IDENTICAL
Operating humidity	10 to 90%	IDENTICAL	IDENTICAL
Average result	7, 14, 30 days pre meal and post meal test average	IDENTICAL	IDENTICAL
Hypoglycemic and hyperglycemic alarm	2 user setting alarms	IDENTICAL	IDENTICAL
Reminder alarm	4 user setting alarms	IDENTICAL	IDENTICAL
PC link Protocol	USB protocol	IDENTICAL	IDENTICAL
Control solution	3 Levels available	IDENTICAL	IDENTICAL
Strip storage temperature	4 to 30 °C (40-86°F)	IDENTICAL	IDENTICAL
Memory capacity	500 test result memories	IDENTICAL	IDENTICAL
Supply power	Two AAA batteries	IDENTICAL	IDENTICAL
Button	Three operating button (M, up and down) One ejection button	IDENTICAL	IDENTICAL

The hematocrit range of proposed devices is 20%~60% by sensing voltage and algorithm change from predicted device.

8. Performance characteristic summary

The performance of TysonBio AC500/AC800/AC500 Pro/AC800 Pro Blood Glucose Monitoring System was studied in the laboratory and in clinical settings by healthcare professionals and lay users. The studies demonstrated that the performance of this system meets its intended use.

9. Conclusion

The TysonBio AC500/AC800/AC500 Pro/AC800 Pro Blood Glucose Monitoring System is substantially equivalent to the predicate device.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 18, 2013

Tyson Bioresearch, Inc.
C/O Wen-Hai Tsai, Ph.D.
5F., #22, Ke E.Road III., Science-Based Industrial Park
CHUN-NAN, MIAO-LI COUNTY, TAIWAN, R.O.C. 350

Re: K123087

Trade/Device Name: TysonBio AC500 Blood Glucose Monitoring System
TysonBio AC800 Blood Glucose Monitoring System
Tyson Bio AC500 Pro Blood Glucose Monitoring System
TysonBio AC800 Pro Blood Glucose monitoring System

Regulation Number: 21 CFR 862.1345

Regulation Name: Glucose test system

Regulatory Class: II

Product Code: NBW, CGA, JJX

Dated: May 18, 2013

Received: May 23, 2013

Dear Dr. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K123087

Device Name: TysonBio AC500 Blood Glucose Monitoring System

Indications for Use:

The TysonBio AC500 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The TysonBio AC500 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The TysonBio AC500 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The TysonBio AC500 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The TysonBio AC500 Test Strips are for use with the TysonBio AC500 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

The TysonBio AC500/AC800 Control Solutions is for use on the TysonBio AC500 Blood Glucose Monitoring Systems to check that the meter and test strips are working together properly and providing accurate results.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiologic Health (OIR)

Katherine Serrano

Division Sign-Off
Office of In Vitro Diagnostics and Radiologic Health

510(k) K123087

Indications for Use Form

510(k) Number (if known): K123087

Device Name: TysonBio AC800 Blood Glucose Monitoring System

Indications for Use:

The TysonBio AC800 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The TysonBio AC800 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The TysonBio AC800 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The TysonBio AC800 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly). The TysonBio AC800 contains a voice function but this function is not intended for users with impaired vision.

The TysonBio AC800 Test Strips are for use with the TysonBio AC800 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

The TysonBio AC500/AC800 Control Solutions is for use on the TysonBio AC800 Blood Glucose Monitoring Systems to check that the meter and test strips are working together properly and providing accurate results.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
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Katherine Serrano

Division Sign-Off
Office of In Vitro Diagnostics and Radiologic Health

510(k) K123087

Indications for Use Form

510(k) Number (if known): K123087

Device Name: TysonBio AC500 Pro Blood Glucose Monitoring System

Indications for Use:

The TysonBio AC500 Pro Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, or forearm. The TysonBio AC500 Pro Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with single-use, auto-disabling lancing devices.

The TysonBio AC500 Pro Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The TysonBio AC500 Pro Blood Glucose Test Strips are for use with the TysonBio AC500 Pro Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

The TysonBio AC500/AC800 Control Solutions is for use on the TysonBio AC500 Pro Blood Glucose Monitoring Systems to check that the meter and test strips are working together properly and providing accurate results.

Prescription Use X AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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510(k) K123087

Indications for Use Form

510(k) Number (if known): K123087

Device Name: TysonBio AC800 Pro Blood Glucose Monitoring System

Indications for Use:

The TysonBio AC800 Pro Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, or forearm. The TysonBio AC800 Pro Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with single-use, auto-disabling lancing devices.

The TysonBio AC800 Pro Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly). The TysonBio AC800 Pro contains a voice function but this function is not intended for users with impaired vision.

The TysonBio AC800 Pro Blood Glucose Test Strips are for use with the TysonBio AC800 Pro Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The TysonBio AC500/AC800 Control Solutions is for use on the TysonBio AC800 Pro Blood Glucose Monitoring Systems to check that the meter and test strips are working together properly and providing accurate results.

Prescription Use X AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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