K112946

TYSON BIORESEARCH, INC.
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510(k) SUMMARY

AUG 2 1 2012

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**
   August 20, 2012

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 MD100 Blood Glucose Monitoring System
   TysonBio MD100 Pro Blood Glucose Monitoring System
   TysonBio MD100 Control Solution
   TysonBio MD100 Test Strip
   TysonBio MD100 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: LFR (Glucose Dehydrogenase, Glucose)
   NBW (System, Test, Blood Glucose, Over The Counter)
   JJX, Single (specified) analyte controls (assayed and unassayed)
   Panel - Clinical Chemistry and Toxicology

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4. Device description

The TysonBio MD100 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 MD100 Test Strips and TysonBio MD100 Control Solution with the TysonBio MD100 Blood Glucose Monitoring System.

The TysonBio MD100 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 MD100 Pro Test Strips and TysonBio MD100 Control Solution with the TysonBio MD100 Pro Blood Glucose Monitoring System.

The TysonBio MD100 / MD100 Pro Blood Glucose Monitoring System consists of:

a. TysonBio MD100/MD100 Pro Blood Glucose Meter
b. TysonBio MD100/MD100 Pro Test Strips
c. TysonBio MD100 Control Solution

5. Intended use

TysonBio MD100 Blood Glucose Monitoring System :

The TysonBio MD100 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in capillary whole blood samples. Capillary samples may be drawn from the fingertip, palm and forearm. The TysonBio MD100 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The TysonBio MD100 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 MD100 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 MD100 Test Strips are for use with the TysonBio MD100 Blood Glucose Meter to quantitatively measure glucose in venous whole blood sample and fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

The TysonBio MD100 Control Solutions is for use on the TysonBio MD100 Blood Glucose Monitoring Systems to check that the meter and test strips are working together properly and providing accurate results.

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TysonBio MD100 Pro Blood Glucose Monitoring System :

The TysonBio MD100 Pro Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in capillary and venous whole blood samples. Capillary samples may be drawn from the fingertip, palm and forearm. The TysonBio MD100 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 auto-disabling, single-use lancing devices. The TysonBio MD100 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 MD100 Pro Blood Glucose Test Strips are for use with the TysonBio MD100 Pro Blood Glucose Meter to quantitatively measure glucose in venous whole blood sample and fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

The TysonBio MD100 Control Solutions is for use on the TysonBio MD100 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 dehydrogenase. There has been no change to the fundamental scientific technology.

7. Predicate device

Ascensia CONTOUR Blood Glucose Monitoring System (K062058)

Item	Predicate Device (K062058)	Proposed Device
	Ascensia Contour Blood Glucose Monitoring System	TysonBio MD100 /MD100 Pro Blood Glucose Monitoring System
Meter size	77 mm (H) x 57 mm (W) x 19 mm (T)	94 mm (H) x 63 mm (W) x 25 mm (T)
Meter weight	47.5 grams	60 grams without battery
Sample volume	0.6uL	0.5uL
AST	Palm, forearm and heel (neonates)	Palm and forearm
Measuring Range	10-600mg/dL	20-600mg/dL
Hematocrit range	0 ~70 %	10-70%
Operating Temperature Range:	5 to 45 ℃ (41-113°F)	10 to 40 ℃ (50-104°F)
Humidity	10-93%	10-90%
Memory Feature	Stores most recent 480 test results	Stores most recent 500 test results
Battery Type:	Two 3-volt lithium batteries (DL2032 or CR2032)	Two AAA batteries
Battery Life:	Approximately 1000 tests (1 yr. average use)	Approximately 1000 tests
Marker	Meal and log book	Meal
Reminder alarm	Post-Meal Test Alarm	4 user setting alarms
Button	Three operating button (M, up and down)	Three operating button (M, up and down) One ejection button

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Similarities:

Item	Predicate Device (K062058)	Proposed Device
	Ascensia Contour Blood Glucose Monitoring System	TysonBio MD100 / MD100 Pro Blood Glucose Monitoring System
Test principle	Electrochemical biosensor with glucose dehydrogenase (FAD)	Electrochemical biosensor with glucose dehydrogenase (FAD)
Test Sample	Whole blood (Capillary and venous blood)	Whole blood (Capillary and venous blood)
Measuring Time	5 seconds	5 seconds
Coding	Auto coding by inserting the test strip	Auto coding by inserting the test strip
Hypoglycemic and hyperglycemic alarm	2 user setting alarms	2 user setting alarms
Average result	7,14 and 30days	7,14 and 30days

8. Performance characteristic summary

The performance of TysonBio MD100 / TysonBio MD100 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 MD100 / MD100 Pro Blood Glucose Monitoring System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Tyson Bioresearch, Inc.
c/o Wen-Hai Tsai
5 F., #22, Ke E. Road III, Science-Based Industrial Park
Chu-Nan, Miao-Li County
China (Taiwan) 350

AUG 2 1 2012

Re: k112916
Trade Name: TysonBio MD100 Blood Glucose Monitoring System
TysonBio MD100 Pro Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, LFR, JJX
Dated: August 9, 2012
Received: August 13, 2012

Dear Wen-Hai 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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

Enclosure

Indication for Use

510(k) Number (if known): k112916

Device Name: TysonBio MD100 Pro Blood Glucose Monitoring System

Indication for Use:

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The TysonBio MD100 Control Solutions is for use on the TysonBio MD100 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
(21 CFR Part 801 Subpart D)	(21 CFR Part 801 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) K112916

Indication for Use

510(k) Number (if known): k112916

Device Name: TysonBio MD100 Blood Glucose Monitoring System

Indication for Use:

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Prescription Use _____	And/Or Over the Counter Use __X__
(21 CFR Part 801 Subpart D)	(21 CFR Part 801 Subpart C)

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

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112916