



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002
October 6, 2017

TYSON BIORESEARCH, INC.
C/O FENG-YU LEE
IVDD REGULATORY CONSULTANT
29222 RANCHO VIEJO ROAD
SAN JUAN CAPISTRANO CA 92675

Re: k170079

Trade/Device Name: Tyson Bio HT100 Blood Glucose Monitoring System
Tyson Bio HT100-B Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW
Dated: September 7, 2017
Received: September 8, 2017

Dear Feng-Yu 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. 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 Parts 801 and 809); 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 regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR 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 Industry and Consumer Education 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,


Kellie B. Kelm -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

510(k) Number (if known)
k170079

Device Name
Tyson Bio HT100-B Blood Glucose Monitoring System

Indications for Use (Describe)

The Tyson Bio HT100-B Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro diagnostic use). It is intended for self-testing by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis of or screening for diabetes or for neonatal use.

The Tyson Bio HT100-B Blood Glucose Monitoring System is comprised of the Tyson Bio HT100-B Blood Glucose Meter and Tyson Bio HT100-B Blood Glucose Test Strip.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Indications for Use

510(k) Number (if known)
k170079

Device Name
Tyson Bio HT100 Blood Glucose Monitoring System

Indications for Use (Describe)

The Tyson Bio HT100 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro diagnostic use). It is intended for self-testing by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis of or screening for diabetes or for neonatal use.

The Tyson Bio HT100 Blood Glucose Monitoring System is comprised of the Tyson Bio HT100 Blood Glucose Meter and Tyson Bio HT100 Blood Glucose Test Strip.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

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

The assigned 510(k) number is: k170079

1. Submitter's Identification:

Tyson Bioresearch, Inc.

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c/o IVDD Regulatory Consultant

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Contact Person: Feng-Yu Lee

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Date Summary Prepared: October 2nd, 2017

2. **Device name and classification**

Device Name:

Tyson Bio HT100 Blood Glucose Monitoring System

Tyson Bio HT100-B Blood Glucose Monitoring System

Common Names:

Blood Glucose Monitoring System

Classification:

Classification Regulation: 21 CFR 862.1345

Classification: Class II (Glucose Test System)

Product Codes :

NBW (System, Test, Blood Glucose, Over-the-Counter)

Panel - Clinical Chemistry and Toxicology

3. Device description

The Tyson Bio HT100 Blood Glucose Monitoring System consists of three main components: the meter, test strip, and control solutions. The system has been designed, tested, and proven to work together as a system accurate blood glucose test results. Use only Tyson Bio HT100 Test Strips and Tyson Bio HT100 Control Solution with the Tyson Bio HT100 Blood Glucose Monitoring System.

The Tyson Bio HT100-B Blood Glucose Monitoring System (with Bluetooth feature) consists of three main components: the meter (with built-in Bluetooth), test strip, and control solutions. The system has been designed, tested, and proven to work together as a system accurate blood glucose test results. Use only Tyson Bio HT100-B Test Strips and Tyson Bio HT100-B Control Solution with the Tyson Bio HT100-B Blood Glucose Monitoring System.

The Tyson Bio HT100 / HT100-B Blood Glucose Monitoring System consists of:

- a. Tyson Bio HT100 / HT100-B Blood Glucose Meter
- b. Tyson Bio HT100 / HT100-B Test Strips

4. Intended use

Tyson Bio HT100 Blood Glucose Monitoring System:

The Tyson Bio HT100 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro diagnostic use). It is intended for self-testing by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis of or screening for diabetes or for neonatal use.

The Tyson Bio HT100 Blood Glucose Monitoring System is comprised of the Tyson Bio HT100 Blood Glucose Meter and Tyson Bio HT100 Blood Glucose Test Strip.

Tyson Bio HT100-B Blood Glucose Monitoring System:

The Tyson Bio HT100-B Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro diagnostic use). It is intended for self-testing by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis of or screening for diabetes or for neonatal use.

The Tyson Bio HT100-B Blood Glucose Monitoring System is comprised of the Tyson Bio HT100-B Blood Glucose Meter and Tyson Bio HT100-B Blood Glucose Test Strip.

5. Test principle

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

6. Predicate device

ACCU-CHEK Performa device (k133741)

6.1 Tyson Bio HT100 Blood Glucose Monitoring System

Differences

Item	Proposed Device	Predicate Device (k133741)
	Tyson Bio HT100 Blood Glucose Monitoring System	ACCU-CHEK Performa Blood Glucose Monitoring System
Enzyme	Electrochemical biosensor with Glucose Dehydrogenase (FAD)	Electrochemical biosensor with Glucose Dehydrogenase – PQQ modified by site-directed mutagenesis (Mutant Q-GDH)
Sample volume	0.7uL	0.6uL
AST	Palm and forearm	-
Hematocrit range	10%~65%	10%~65%
Operating Temperature Range:	10 to 40 °C (50-104°F)	16 to 35 °C (61-95°F)
Humidity	10-90%	10-80%
Coding	Auto coding test strip	Code key inserts directly into code key slot in meter.
Battery Type:	Two AAA batteries	One CR2032
Reminder alarm	4 user setting alarms	Post-Meal Test Alarm
Button	Three operating button (M, up and down) One ejection button	Three operating buttons (Power, up and down)
Meter size	106 x 66 x 20 mm (LWH)	93 x 52 x 22 mm (LWH)
Meter weight	65 grams without battery	Approx. 62 grams (with battery)

Similarities

Item	Proposed Device	Predicate Device (k133741)
	Tyson Bio HT100 Blood Glucose Monitoring System	ACCU-CHEK Performa Blood Glucose Monitoring System
Intended Use	Over-The-Counter Quantitative measurement of glucose (sugar) in fresh capillary whole blood samples.	
Test principle	Amperometric detection	
Test Sample	Capillary Whole Blood from Fingertip	
Measuring Range	20-600mg/dL	
Memory capacity	500 results with time and date	

6.2 Tyson Bio HT100-B Blood Glucose Monitoring System

Differences

Item	Proposed Device	Predicate Device (k133741)
	Tyson Bio-B HT100 Blood Glucose Monitoring System	ACCU-CHEK Performa Blood Glucose Monitoring System
Enzyme	Electrochemical biosensor with Glucose Dehydrogenase (FAD)	Electrochemical biosensor with Glucose Dehydrogenase – PQQ modified by site-directed mutagenesis (Mutant Q-GDH)
Sample volume	0.7uL	0.6uL
AST	Palm and forearm	-
Hematocrit range	10%~65%	10%~65%
Operating Temperature Range:	10 to 40 °C (50-104°F)	16 to 35 °C (61-95°F)
Humidity	10-90%	10-80%
Coding	Auto coding test strip	Code key inserts directly into code key slot in meter.
Battery Type:	Two AAA batteries	One CR2032
Reminder alarm	4 user setting alarms	Post-Meal Test Alarm
Button	Three operating button (M, up and down) One ejection button	Three operating buttons (Power, up and down)
Meter size	106 x 66 x 20 mm (LWH)	93 x 52 x 22 mm (LWH)
Meter weight	65 grams without battery	Approx. 62 grams (with battery)
Bluetooth	Yes	No

Similarities

Item	Proposed Device	Predicate Device (k133741)
	Tyson Bio HT100-B Blood Glucose Monitoring System	ACCU-CHEK Performa Blood Glucose Monitoring System
Intended Use	Over-The-Counter Quantitative measurement of glucose (sugar) in fresh capillary whole blood samples.	
Test principle	Amperometric detection	
Test Sample	Capillary Whole Blood from Fingertip	
Measuring Range	20-600mg/dL	
Memory capacity	500 results with time and date	

7. Performance characteristic summary

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:

Verification and validation of these blood glucose systems evaluated to establish the performance, functionality, and reliability of the Tyson Bio HT100 Blood Glucose Monitoring System, and Tyson Bio HT100-B Blood Glucose Monitoring System. The evaluation included precision, linearity, interference, sample volume and hematocrit.

Discussion of Clinical Tests Performed:

Method Comparison / System Accuracy Study:

The system accuracy study of the Tyson Bio HT100 Blood Glucose Monitoring System and Tyson Bio HT100-B Blood Glucose Monitoring System was performed by comparing capillary whole blood glucose values on the Tyson Bio HT100 Blood Glucose Monitoring System with glucose values on lab instrument YSI 2300 Plus Glucose Analyzer.

A total of 127 patients participated. The study results demonstrate that the accuracy of Tyson Bio HT100 Blood Glucose Monitoring System met the acceptance criteria.

Values obtained from meters compared with YSI results; linear results regression analysis yielded the following results:

Fingertip	Predicate device	Proposed Devices Tyson Bio HT100		
	Performa	LOT 1	LOT 2	LOT 3
N	127	127	127	127
Slope	0.969	0.988	1.004	0.998
Intercept	2.408	1.950	1.684	0.504
R2	0.9871	0.9921	0.9874	0.9887

Combined Tyson Bio HT100 three lots yield the following result:

Regression	$y=0.9966x+0.0053$
95% CI of slope	0.9861 to 1.007
95% CI of intercept	-0.7270 to 3.487
R2	0.9892

User Performance Study:

The user performance study was performed to demonstrate that English speaking and reading lay users across all educational backgrounds can easily understand and follow the labeling/user instructions to obtain accurate results while using Tyson Bio HT100 Blood Glucose Monitoring System and Tyson Bio HT100-B Blood Glucose Monitoring System.

A total of 121 subjects participated. The study results demonstrate that the user accuracy and ease of use (via participant questionnaire scoring) Tyson Bio HT100 Blood Glucose Monitoring System and Tyson Bio HT100-B Blood Glucose Monitoring System meet the acceptance criteria.

8. Conclusion

The Tyson Bio HT100 and HT100-B Blood Glucose Monitoring Systems are substantially equivalent to the predicate device.