November 29, 2018

Tyson Bioresearch, Inc.
% Feng- Yu Lee, Regulatory Consultant
Dynamic Biotech Inc. dba IVDD Regulatory Consultant
29222 Rancho Viejo Road, Suite 218
San Juan Capistrano, CA 92675

Re: K182047
Trade/Device Name: Tyson Bio HT100-A Blood Glucose Monitoring System
Tyson Bio HT100-C Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: October 25, 2018
Received: October 30, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

k182047

Device Name
Tyson Bio HT100-A Blood Glucose Monitoring System

Indications for Use *(Describe)*

The Tyson Bio HT100-A 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. Alterative 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-A Blood Glucose Monitoring System is comprised of the Tyson Bio HT100-A Blood Glucose Meter and Tyson Bio 50H 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

k182047

Device Name
Tyson Bio HT100-C Blood Glucose Monitoring System

Indications for Use *(Describe)*

The Tyson Bio HT100-C 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. Alterative 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-C Blood Glucose Monitoring System is comprised of the Tyson Bio HT100-C Blood Glucose Meter and Tyson Bio 50H 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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www.tysonbio.com

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: k182047

1. Submitter's Identification:

Tyson Bioresearch, Inc.
5F, No.16, 18, 20, 22, Kedong 3rd Rd.,
Zhunan Township, Miaoli County 35053, Taiwan (R.O.C.)
Correspondent:
VANCE CHANG
Phone: 886-37-585988 EXT 12001
Facsimile: 886-37-585996

Feng-Yu Lee
c/o IVDD Regulatory Consultant
29222 Rancho Viejo Road, Suite 218
San Juan Capistrano, CA 92675
Contact Person: Feng-Yu Lee
Phone Number: 1-949-218-0929
Fax Number: 1-949-218-0928

Date Summary Prepared: November 27th, 2018

2. Device name and classification

Device Name:

Tyson Bio HT100-A Blood Glucose Monitoring System

Tyson Bio HT100-C Blood Glucose Monitoring System

Common Names:

Blood Glucose Monitoring System

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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-A Blood Glucose Monitoring System (with Voice feature) consists of three main components: the meter (with built-in Voice feature), test strip, and control solutions. The system has been designed, tested, and proven to work together as a system accurate blood glucose test results. Tyson Bio 50H Blood Glucose Test Strip (Test Strips are the same as k170079) and Tyson Bio 50H Control Solution (Control Solutions are the same as k170079) can be used with the Tyson Bio HT100-A Blood Glucose Monitoring System.

The Tyson Bio HT100-C Blood Glucose Monitoring System (with Voice and Bluetooth features) consists of three main components: the meter (with built-in Voice and Bluetooth features), test strip, and control solutions. The system has been designed, tested, and proven to work together as a system accurate blood glucose test results. Tyson Bio 50H Blood Glucose Test Strip (Test Strips are the same as k170079) and Tyson Bio 50H Control Solutions (Control Solutions are the same as k170079) can be used with the Tyson Bio HT100-C Blood Glucose Monitoring System.

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

a. Tyson Bio HT100-A / HT100-C Blood Glucose Meter
b. Tyson Bio 50H Test Strips
   (Test Strips are the same as k170079)

4. Intended use

Tyson Bio HT100-A Blood Glucose Monitoring System:

The Tyson Bio HT100-A 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. Alterative 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.

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The Tyson Bio HT100-A Blood Glucose Monitoring System is comprised of the Tyson Bio HT100-A Blood Glucose Meter and Tyson Bio 50H Blood Glucose Test Strip.

Tyson Bio HT100-C Blood Glucose Monitoring System:

The Tyson Bio HT100-C 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. Alterative 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-C Blood Glucose Monitoring System is comprised of the Tyson Bio HT100-C Blood Glucose Meter and Tyson Bio 50H 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

Tyson Bio HT100 Blood Glucose Monitoring System (k170079) for HT100-A

Tyson Bio HT100-B Blood Glucose Monitoring System (k170079) for HT100-C

6.1 Tyson Bio HT100-A Blood Glucose Monitoring System

Similarities

Item	Predicate device (k170079)	Proposed Device
	Tyson Bio HT100 Blood Glucose Monitoring System	**Tyson Bio HT100-A Blood Glucose Monitoring System**
Intended Use	Over-The-Counter Quantitative measurement of glucose (sugar) in fresh capillary whole blood samples.	
Enzyme	Electrochemical biosensor with Glucose Dehydrogenase (FAD)	
Test Principle	Amperometric detection	
Measuring Range	20-600mg/dL	
Hematocrit Range	10%-65%	
Sample Volume	0.7uL	

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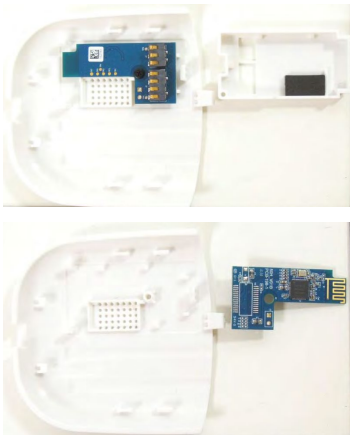
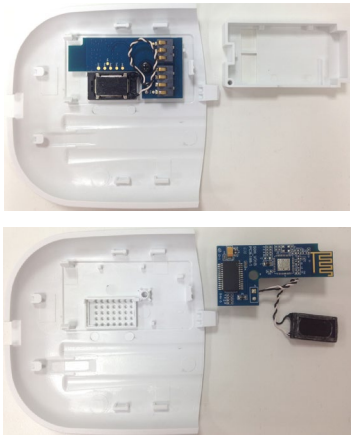
AST	Palm and forearm
Coding	Auto coding test strip
Operating Temperature Range	10-40 ℃ (50-104℉)
Operating Humidity Range	10-90%
Memory Capacity	500 results with time and date
Battery Type	Two AAA batteries
Reminder Alarm	4 user setting alarms
Button	Three operating button (M, up and down) One ejection button
Meter Size	106 x 66 x 20 mm (LWH)
Bluetooth	No

Differences

Item	**Predicate device (k170079)**	**Proposed Device**
	Tyson Bio HT100 Blood Glucose Monitoring System	**Tyson Bio HT100-A Blood Glucose Monitoring System**
Voice	No	Yes
Meter Weight	65 grams without battery	69.8 grams without battery
Functional Back Cover Open View		

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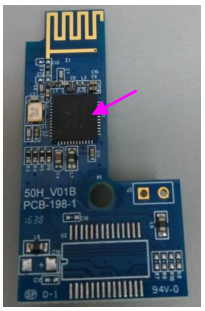
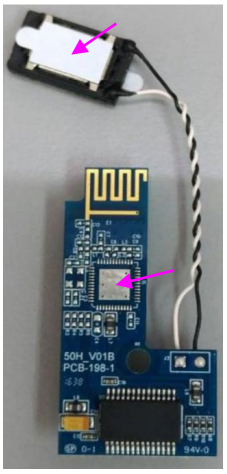
Functional Back Cover PCBA	Front  Back 	Front  Back 

6.2 Tyson Bio HT100-C Blood Glucose Monitoring System

Similarities

Item	**Predicate device (k170079)**	**Proposed Device**
	Tyson Bio HT100-B Blood Glucose Monitoring System	**Tyson Bio HT100-C Blood Glucose Monitoring System**
Intended Use	Over-The-Counter Quantitative measurement of glucose (sugar) in fresh capillary whole blood samples.	
Enzyme	Electrochemical biosensor with Glucose Dehydrogenase (FAD)	

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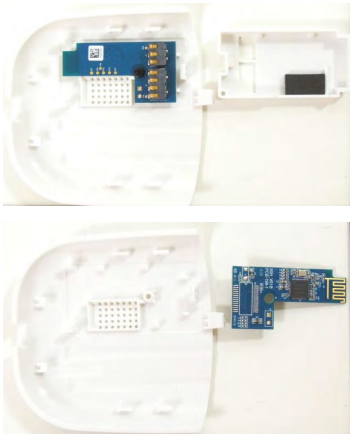
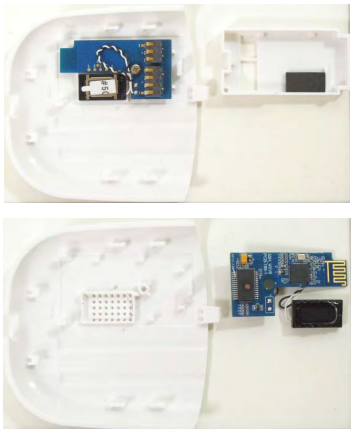
Test Principle	Amperometric detection
Measuring Range	20-600mg/dL
Hematocrit Range	10%-65%
Sample Volume	0.7uL
AST	Palm and forearm
Coding	Auto coding test strip
Operating Temperature Range	10-40 ℃ (50-104˚F)
Operating Humidity Range	10-90%
Memory Capacity	500 results with time and date
Battery Type	Two AAA batteries
Reminder Alarm	4 user setting alarms
Button	Three operating button (M, up and down) One ejection button
Meter Size	106 x 66 x 20 mm (LWH)
Bluetooth	Yes

Differences

Item	**Predicate device(k170079)**	**Proposed Device**
	Tyson Bio HT100-B Blood Glucose Monitoring System	**Tyson Bio HT100-C Blood Glucose Monitoring System**
Voice	No	Yes
Meter Weight	65 grams without battery	70 grams without battery
Functional Back Cover Open View		

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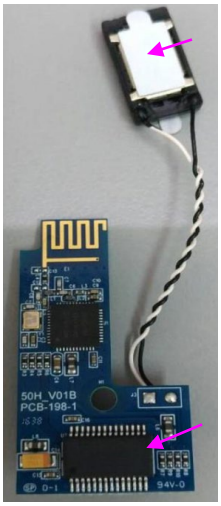
Functional Back Cover PCBA	Front  Back 	Front  Back 

7. Conclusion

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