November 30, 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: K182046
Trade/Device Name: Tyson Bio HS100 Blood Glucose Monitoring System
Tyson Bio HS100-B Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: October 31, 2018
Received: October 31, 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)*

k182046

Device Name
Tyson Bio HS100 Blood Glucose Monitoring System

Indications for Use *(Describe)*

The Tyson Bio HS100 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 HS100 Blood Glucose Monitoring System is comprised of the Tyson Bio HS100 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)*

k182046

Device Name
Tyson Bio HS100-B Blood Glucose Monitoring System

Indications for Use *(Describe)*

The Tyson Bio HS100-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. 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 HS100-B Blood Glucose Monitoring System is comprised of the Tyson Bio HS100-B 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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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: k182046

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

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 28th, 2018

2. Device name and classification

Device Name:

Tyson Bio HS100 Blood Glucose Monitoring System

Tyson Bio HS100-B 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 HS100 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. 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 HS100 Blood Glucose Monitoring System.

The Tyson Bio HS100-B Blood Glucose Monitoring System consists of three main components: the meter (with Bluetooth 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 Solutions (Control Solutions are the same as k170079) can be used with the Tyson Bio HS100-B Blood Glucose Monitoring System.

The Tyson Bio HS100 / HS100-B Blood Glucose Monitoring System consists of:

a. Tyson Bio HS100 / HS100-B Blood Glucose Meter
b. Tyson Bio 50H Blood Glucose Test Strips
   (Test Strips are the same as k170079)

4. Intended use

Tyson Bio HS100 Blood Glucose Monitoring System:

The Tyson Bio HS100 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 HS100 Blood Glucose Monitoring System is comprised of the Tyson Bio HS100 Blood Glucose Meter and Tyson Bio 50H Blood Glucose Test Strip.

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Tyson Bio HS100-B Blood Glucose Monitoring System:

The Tyson Bio HS100-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. 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 HS100-B Blood Glucose Monitoring System is comprised of the Tyson Bio HS100-B 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 HS100

Tyson Bio HT100-B Blood Glucose Monitoring System (k170079) for HS100-B

6.1 Tyson Bio HS100 Blood Glucose Monitoring System

Similarities:

Item	Predicate device (k170079)	Proposed Device
	Tyson Bio HT100 Blood Glucose Monitoring System	**Tyson Bio HS100 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	
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	
Bluetooth	No	

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Differences:

The item list of differences from predicate device:

(1) Meter size change
(2) Ejection button color change
(3) Ejection button position change
(4) Operation button size change
(5) Removal of USB transfer:
(6) LCD interface change- "Month" and "Day" are displayed in the upper left corner of the LCD screen
(7) LCD interface change- Remove one display bar in the upper left corner of the LCD screen
(8) LCD interface change- Remove “AM” in the upper right corner of the LCD screen.
(9) User interface change-"Month" and "Day" are displayed on the LCD when user doing:
- Date Setup
- Blood Glucose Measurement
- Control Solution Measurement
- View the memory for blood glucose measurement
- View the memory for control solution measurement

(10) Removal of Bluetooth function

The rationales of differences from predicate device:

(1) Meter size change:
For product portfolio plan, a smaller size with less cost is offered to customer.
(2) Ejection button color change:
Separate the color of the housing to make the ejection button more easily to be seen.
(3) Ejection button position change:
Change the ejection button from the lower half of the meter to the upper half, which is a requirement from potential customers.
(4) Operation button size change:
The three-dimensional raised button design is more noticeable for user to operate.
(5) Removal of USB transfer:
Simplify the data transfer function of meter.
(6) LCD interface change- "Month" and "Day" are displayed in the upper left corner of the LCD screen:
Give the meanings of numbers which are displayed in the upper left corner of the LCD.
(7) LCD interface change- Remove one display bar in the upper left corner of the LCD screen:
Removing this display bar will not affect the date and time display of the instrument and can reduce costs.
(8) LCD interface change- Remove “AM” in the upper right corner of the LCD screen.
Removing “AM” will not affect the date and time display of the meter and can reduce costs.
(9) User interface change-"Month" and "Day" are displayed on the LCD when user doing:
- Date Setup
- Blood Glucose Measurement
- Control Solution Measurement
- View the memory for blood glucose measurement
- View the memory for control solution measurement

Give the meanings of numbers which are displayed in the upper left corner of the LCD.
(10) Removal of Bluetooth function:
Simplify the data transfer function of meter.

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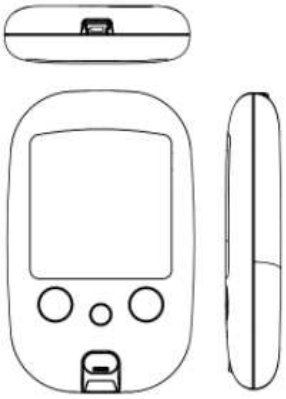
Item	Predicate Device (k170079) Tyson Bio HT100 Blood Glucose Monitoring System	Proposed Device Tyson Bio HS100 Blood Glucose Monitoring System
Meter Appearance		
	Meter Size: 106 x 66 x 20 mm (LWH)	**Meter Size:** 108 x 55 x 15 mm (LWH)
	Ejection button Color: White	**Ejection button Color:** Orange
	Ejection button position: The lower half of the meter	**Ejection button position:** The upper half of the meter
	Three-view drawing: 	**Three-view drawing:** 

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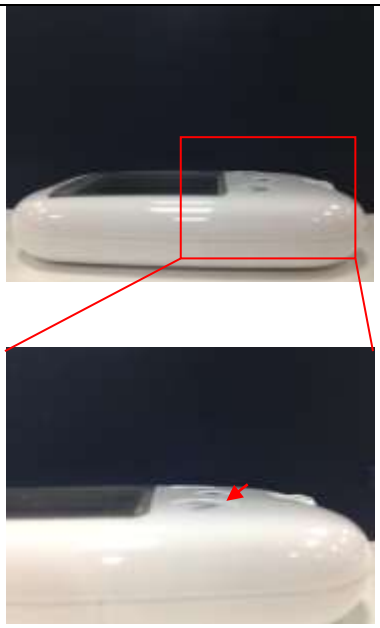
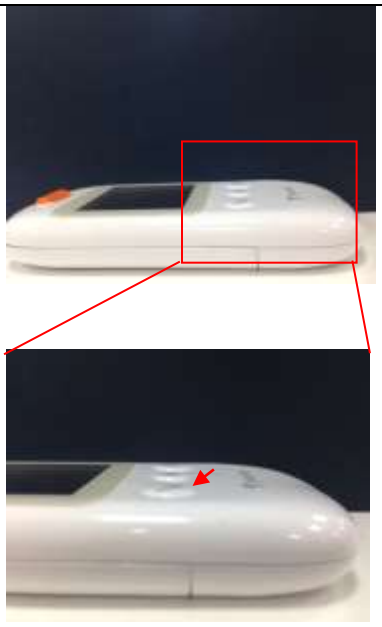
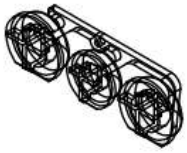
Item	Predicate Device (k170079) Tyson Bio HT100 Blood Glucose Monitoring System	Proposed Device Tyson Bio HS100 Blood Glucose Monitoring System
Operating Buttons		
		
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	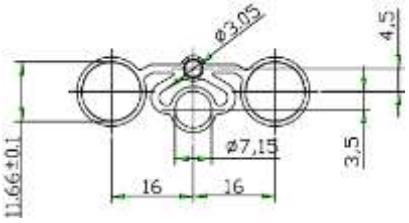	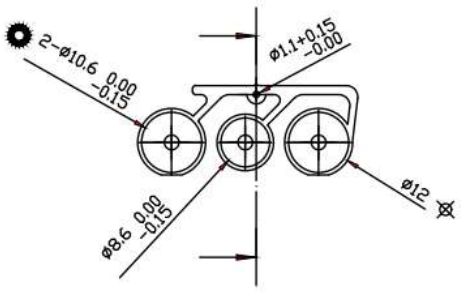
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	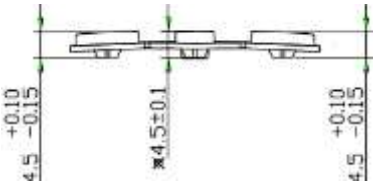	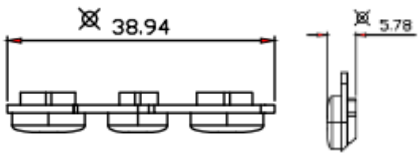
	Back:	**Back:**

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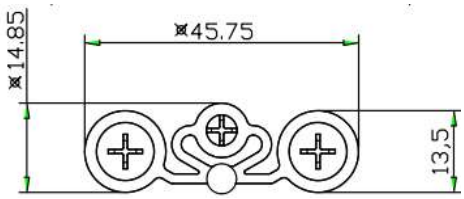
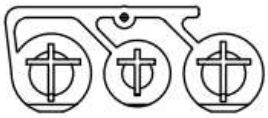
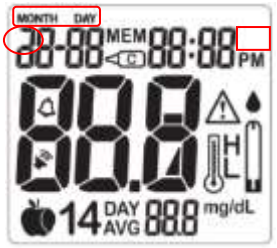
Item	Predicate Device (k170079) Tyson Bio HT100 Blood Glucose Monitoring System	Proposed Device Tyson Bio HS100 Blood Glucose Monitoring System
		
USB Interface	Yes	No
LCD Display		 Circled icons are the difference with respect to predicate device (k170079).
User Interface	**Date Setup:** 	**Date Setup:**  Circled icons are the difference with respect to predicate device (k170079). Indications of "Month" and "Day" are applied.
	Blood Glucose Measurement Display: 	**Blood Glucose Measurement Display:**  Circled icons are the difference with respect to predicate device (k170079). Indications of "Month" and "Day" are applied.

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Item	Predicate Device (k170079) Tyson Bio HT100 Blood Glucose Monitoring System	Proposed Device Tyson Bio HS100 Blood Glucose Monitoring System
	Control Solution Measurement Display:  	**Control Solution Measurement Display:**  Circled icons are the difference with respect to predicate device (k170079). Indications of "Month" and "Day" are applied.
	Memory Display for Blood Glucose Measurement:  	**Memory Display for Blood Glucose Measurement:**  Circled icons are the difference with respect to predicate device (k170079). Indications of "Month" and "Day" are applied.
	Memory Display for Control Solution Measurement:  	**Memory Display for Control Solution Measurement:**  Circled icons are the difference with respect to predicate device (k170079). Indications of "Month" and "Day" are applied.
Bluetooth	Yes	No

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6.2 Tyson Bio HS100-B Blood Glucose Monitoring System

Similarities:

Item	Predicate device (k170079)	Proposed Device
	Tyson Bio HT100-B Blood Glucose Monitoring System	**Tyson Bio HS100-B 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	
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	
Bluetooth	Yes	

Differences:

The item list of differences from predicate device:

(1) Meter size change
(2) Ejection button color change
(3) Ejection button position change
(4) Operation button size change
(5) Removal of USB transfer:
(6) LCD interface change- "Month" and "Day" are displayed in the upper left corner of the LCD screen
(7) LCD interface change- Remove one display bar in the upper left corner of the LCD screen
(8) LCD interface change- Remove “AM” in the upper right corner of the LCD screen.
(9) User interface change-"Month" and "Day" are displayed on the LCD when user doing:
- Date Setup
- Blood Glucose Measurement
- Control Solution Measurement
- View the memory for blood glucose measurement
- View the memory for control solution measurement

The rationales of differences from predicate device:

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(1) Meter size change:
For product portfolio plan, a smaller size with less cost is offered to customer.
(2) Ejection button color change:
Separate the color of the housing to make the ejection button more easily to be seen.
(3) Ejection button position change:
Change the ejection button from the lower half of the meter to the upper half, which is a requirement from potential customers.
(4) Operation button size change:
The three-dimensional raised button design is more noticeable for user to operate.
(5) Removal of USB transfer:
Simplify the data transfer function of meter.
(6) LCD interface change- "Month" and "Day" are displayed in the upper left corner of the LCD screen:
Give the meanings of numbers which are displayed in the upper left corner of the LCD.
(7) LCD interface change- Remove one display bar in the upper left corner of the LCD screen:
Removing this display bar will not affect the date and time display of the meter and can reduce costs.
(8) LCD interface change- Remove “AM” in the upper right corner of the LCD screen.
Removing “AM” will not affect the date and time display of the meter and can reduce costs.
(9) User interface change-"Month" and "Day" are displayed on the LCD when user doing:

- Date Setup
- Blood Glucose Measurement
- Control Solution Measurement
- View the memory for blood glucose measurement
- View the memory for control solution measurement

Give the meanings of numbers which are displayed in the upper left corner of the LCD.

Item	**Predicate Device (k170079)**	**Proposed Device**
	Tyson Bio HT100-B Blood Glucose Monitoring System	**Tyson Bio HS100-B Blood Glucose Monitoring System**
Meter Appearance		
	Meter Size: 106 x 66 x 20 mm (LWH)	**Meter Size:** 108 x 55 x 15 mm (LWH)

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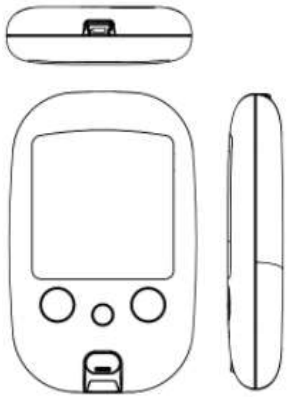
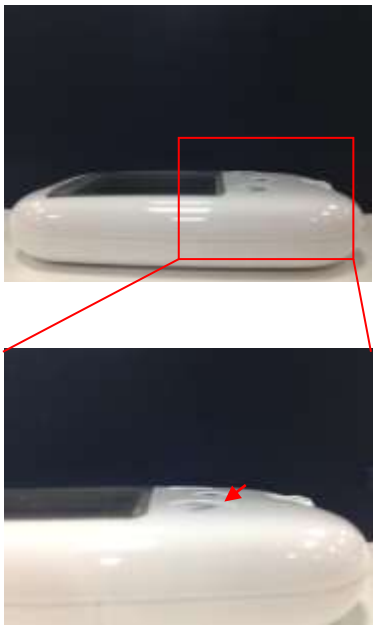
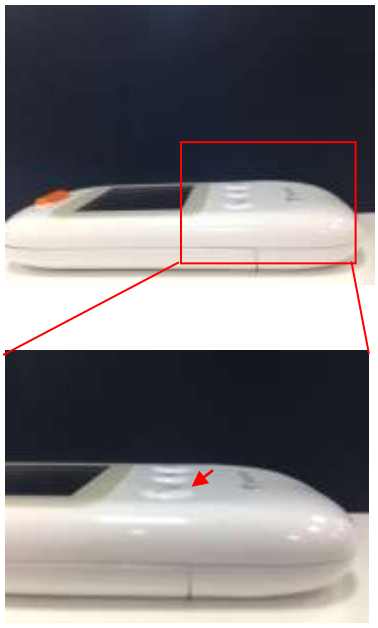
Item	Predicate Device (k170079) Tyson Bio HT100-B Blood Glucose Monitoring System	Proposed Device Tyson Bio HS100-B Blood Glucose Monitoring System
	Ejection button Color: White	**Ejection button Color:** Orange
	Ejection button position: The lower half of the meter	**Ejection button position:** The upper half of the meter
	Three-view drawing: 	**Three-view drawing:** 
Operating Buttons		

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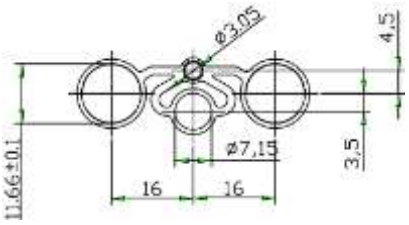
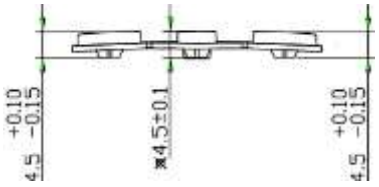
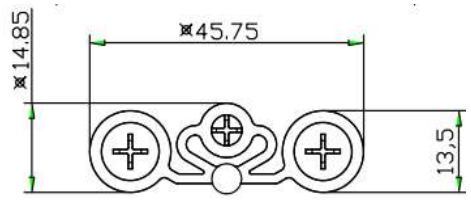
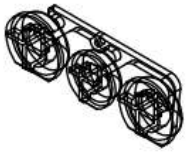
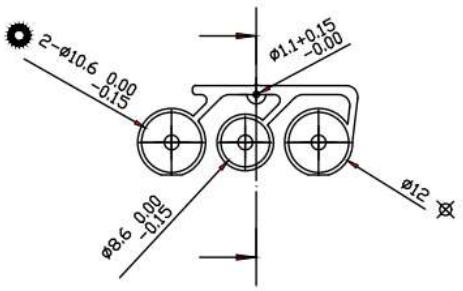
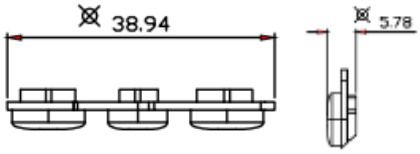
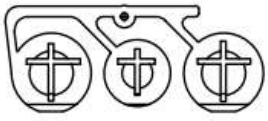
Item	Predicate Device (k170079) Tyson Bio HT100-B Blood Glucose Monitoring System	Proposed Device Tyson Bio HS100-B Blood Glucose Monitoring System
	 **Front:**  **Side:**  **Back:** 	 **Front:**  **Side:**  **Back:** 
USB Interface	Yes	No
LCD Display		

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Item	Predicate Device (k170079) Tyson Bio HT100-B Blood Glucose Monitoring System	Proposed Device Tyson Bio HS100-B Blood Glucose Monitoring System
		Circled icons are the difference with respect to predicate device (k170079).
User Interface	**Date Setup:** 	**Date Setup:**  Circled icons are the difference with respect to predicate device (k170079). Indications of "Month" and "Day" are applied.
	Blood Glucose Measurement Display: 	**Blood Glucose Measurement Display:**  Circled icons are the difference with respect to predicate device (k170079). Indications of "Month" and "Day" are applied.
	Control Solution Measurement Display: 	**Control Solution Measurement Display:**  Circled icons are the difference with respect to predicate device (k170079). Indications of "Month" and "Day" are applied.
	Memory Display for Blood Glucose Measurement:	**Memory Display for Blood Glucose Measurement:**

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Item	Predicate Device (k170079) Tyson Bio HT100-B Blood Glucose Monitoring System	Proposed Device Tyson Bio HS100-B Blood Glucose Monitoring System
		 Circled icons are the difference with respect to predicate device (k170079). Indications of "Month" and "Day" are applied.
	Memory Display for Control Solution Measurement: 	**Memory Display for Control Solution Measurement:**  Circled icons are the difference with respect to predicate device (k170079). Indications of "Month" and "Day" are applied.

7. Conclusion

The Tyson Bio HS100 and HS100-B Blood Glucose Monitoring Systems are substantially equivalent to the predicate device.