DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

September 15, 2017

BIOTEST MEDICAL CORPORATION
FRED LEE
ENGINEERING/REGULATORY MANAGER
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TAICHUNG 42760
TW

Re: k171785
Trade/Device Name: WowGoHealth Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW
Dated: August 16, 2017
Received: August 18, 2017

Dear Fred 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

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)*
K171785

Device Name
WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902)

Indications for Use *(Describe)*
WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902)

The WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902) consists of the WowGoHealth Blood Glucose Monitor and the WowGoHealth Blood Glucose Test Strip. The WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902) is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips or forearm. The WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902) is intended to be used by a single person and should not be shared.

The WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902) is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of a diabetes control program.

The WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902) 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).

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

510K # (K171785)

Date Prepared:

September 13, 2017

510(k) Type:

Special (Device Modification)

Submitter Information: *21 CFR 807.92(a)(1)*

Establishment Name: Biotest Medical Corporation

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Device Name: *21 CFR 807.92(a)(2)*

Trade/Device Name: WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902)

Regulation Number: 862.1345

Regulation Name: Glucose test system

Regulatory Class: II

Product code: NBW, Over-the Counter

Predicate Device: 21 CFR 807.92(a)(3)

Device Classification Name	System, Test, Blood Glucose, Over The Counter
510(K) Number	K141351
Device Name	SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S)
Regulation Number	862.1345
Classification Product Code	NBW
Date Received	05/22/2014
Decision Date	05/19/2015
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Clinical Chemistry
510k Review Panel	Clinical Chemistry
Type	Traditional
Combination Product	No

Device Description: *21 CFR 807.92(a)(4)*

✓ **General device description:**

- Physical components of the system

  The WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902) is a product kit consisting of a blood glucose meter (meter), test strips, a lancing device, lancets, and

instructions for use. Control solution Level 1, Level 2 or 3 are available and sold separately. Fig. 1 provides an image of the device, showing the front front/side angle and the back of the device and with the meter's components annotated.

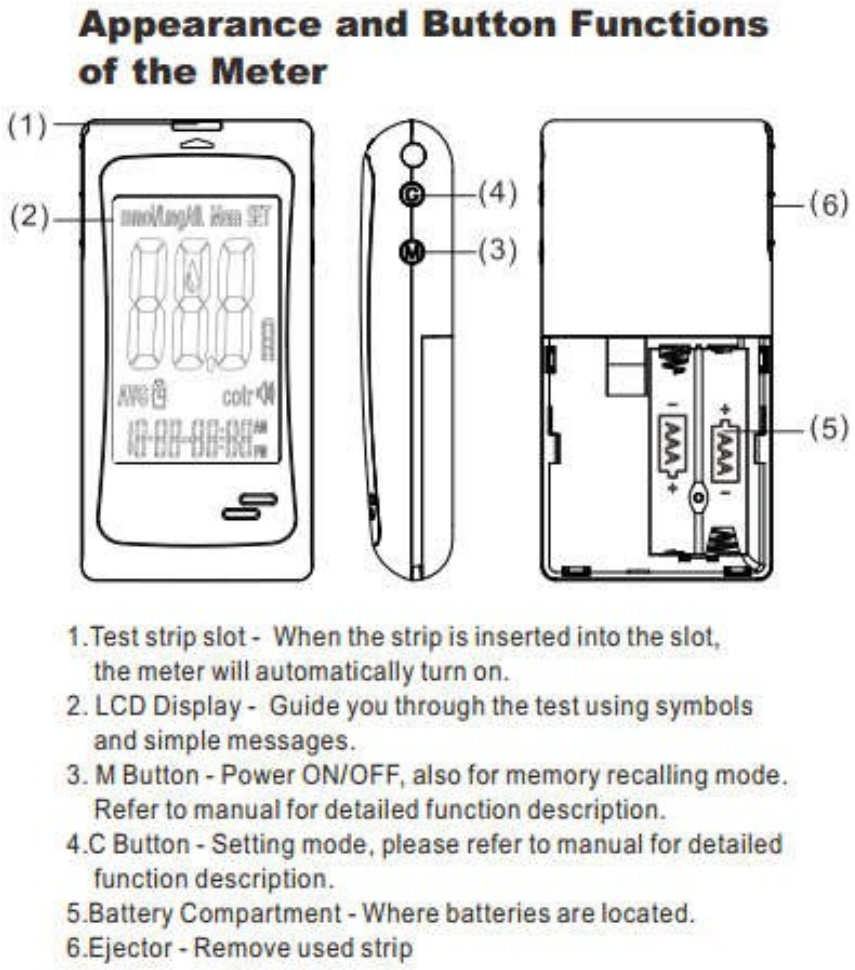


Fig. 1 WowGoHealth, Model GSH-BGM902 with its components annotated

- Test principle

  When glucose reacts with the reagents on the test strips, an electrical current is produced. The current is proportional to the glucose concentration in the blood sample. The meter will calculate glucose concentration based on the current measured.

- Format of results

  The device can show results either in "mg/dL" or "mmol/L". The factory set default for the meter is mg/dL.

- Composition and levels of control material

  The control solution is made up of D-glucose, Viscosity Modifier, and Preservatives. Control solution Level 1, Level 2 or 3 are available and sold separately.

- User maintenance needs

  The device is recommended to be stored in its case, in a clean dry place at 35.6 to 86°F

(2 to 30℃).

Replacing the battery will not reset the stored testing results; however users need to reset the device's date and time after installing or replacing the batteries.

- Features of device

  Apart from the existing measurement features and user interface of the device's predicate, the device is featured with Bluetooth mediated data transmission functionality which wirelessly transfers the latest test result to an APP run on a mobile device every time when a test is performed successfully. In this operational scenario, the user needs to install an APP to his/her mobile device to receive the test result transmitted from the meter; in case the data transmission fails, user can still manually enter the test result to the APP. The meter does not play any message during the data transmission, but user can check the APP on his/her mobile device to confirm if the test result is received. The meter still keeps the test results in the memory after transmitting.

- Features designed to minimize the risk of bloodborne pathogen transmission among patients

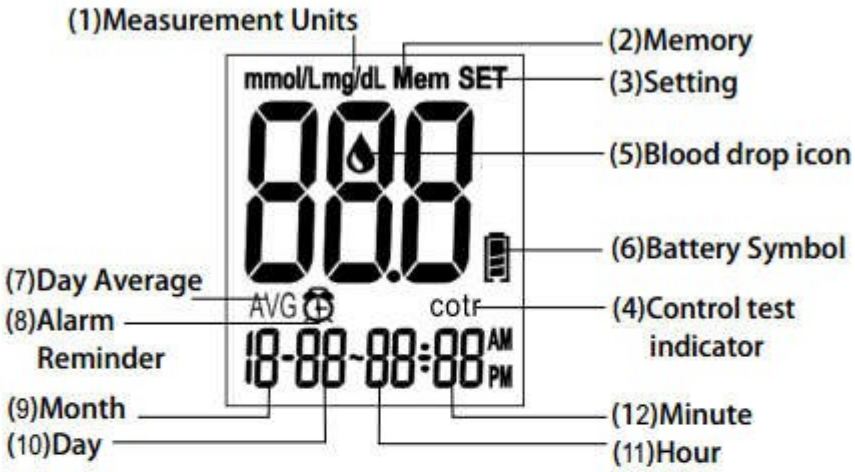
  Users are recommended to clean and disinfect the meter and lancing device at least once per week following the Cleaning and Disinfection Instructions in device's user guide to prevent the spread of infectious diseases. Clorox® Bleach Germicidal Wipes (EPA Reg. No. 67619-12) have been shown to be safe for use with the meter and lancing device and that these wipe should be used for both cleaning and disinfection.

✓ **Device features controlled by the software:**

- Displays and user messages

  Refer to Fig. 2 for details.

Meter Display



1.Appears with the test result either in mg/dL or in mmol/L.
2.Appears when you recall the memory.
3.Appears when you are in start up mode or setting mode.
4.Appears for control solution test flag.
5.Indicates the meter is ready to take the blood sample when it flashes.
6.Indicates the battery status.
7.Indicates current displayed result is an average.
8.Appears when alarm is on.
9.Month
10.Day
11.Hour
12.Minute

Fig. 2 Meter's Displays and user messages

- Error messages

  The meter is featured with the following error messages for users to understand the device's status so as to take appropriate measures.

  E_1: The temperature is too low.

  E_2: The temperature is too high.

  E_3: Battery Low.

  E_4: Memory damaged.

  E_5: The strip is wet or used.

  E_6: Error in meter or strip.

  E_7: The blood sample is not sufficient.

  HI: The glucose level is too high.

  LO: The glucose level is too low.

- User prompts

To perform a test, a glucose test strip is inserted into the top of the meter (meter). When a small drop of blood is applied to the end of the test strip, glucose reacts with the reagents on the test strips, producing an electrical current that is proportional to the blood glucose concentration in the blood sample. The blood glucose concentration is calculated by the glucose meter and is based on the electrical current measured. The quantitative glucose concentration (in mg/dL or mmol/L) is displayed on the meter's LCD screen.

- Alarms and other feed back

  The meter is featured with an alarm clock which can be used as a reminder to users for time to measure his/her blood glucose.

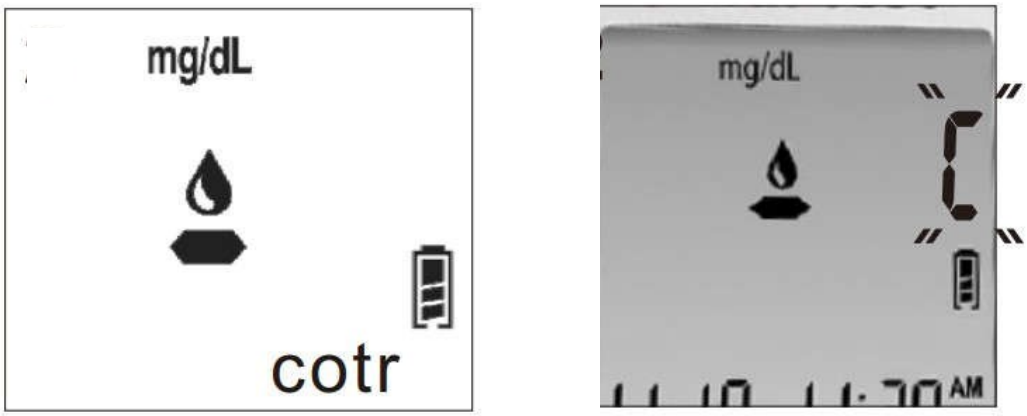
✓ **Modified Device and Comparison:**

The test strips, control solutions, lancing device, and lancets are identical to previously cleared devices. The fundamental scientific technology of the WowGoHealth, Model GSH-BGM902 remains unchanged from the legally marketed predicate device, SuperCheck Plus, Model 5228-S (K141351).

For the proposed WowGoHealth, Model GSH-BGM902 device, the modifications from the cleared SuperCheck Plus, Model 5228-S (K141351), are minor and include the following:

- Reposition of the control test flag ("cotr") on meter display (see Fig.2)

  This original control test flag ("C") was displayed via a 7-segment font to the right of the three large 7-segment fonts for glucose reading display. This difference is concretely illustrated in Fig.3.



WowGoHealth SuperCheck Plus

Fig.3. Meter display while performing the control test

- Bluetooth mediated data transmission functionality to replace the original RS232 cable

  Owing to the meter 's Bluetooth mediated data transmission functionality supporting Bluetooth 4.0 and BLP, the WowGoHealth, Model GSH-BGM902 has the capability to wirelessly transfer the latest test result to an APP run on a mobile device every time when a test is performed successfully. In this operational scenario, the user needs to install an APP to his/her mobile device to receive the test result transmitted from the

meter; in case the data transmission fails, user can still manually enter the test result to the APP. During the wireless data transmission, the "**bLE**" and test time on meter's display would flash alternately (see Fig. 4). The meter does not play any message during the data transmission, but user can check the APP on his/her mobile device to confirm if the test result is received. The meter still keeps the test results in the meter.

Fig. 4 "**bLE**" and test time on meter's display flash alternately during data transmission

- Change of meter's housing color

  The quality of meter's housing materials remains unchanged except the color is changed from black to white.

Fig. 5 Meter's physical appearance/WowGoHealth, Model GSH-BGM902

- User Manual Modifications

  Minor modifications to the WowGoHealth, Model GSH-BGM902 User Manual have been made to accommodate changes from the predicate device and facilitate use of the device. These changes are detailed in submitted labeling of this application, and the intended use of the WowGoHealth, Model GSH-BGM902 has not changed as a result of these modifications.

Intended Use/Indications for use: *21 CFR 807.92(a)(5)*

WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902)

The WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902) consists of the WowGoHealth Blood Glucose Monitor and the WowGoHealth Blood Glucose Test Strip. The WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902) is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips or forearm. The WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902) is intended to be used by a single person and should not be shared.

The WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902) is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in Monitoring the effectiveness of a diabetes control program.

The WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902) 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).

Technical characteristics against the predicate: *21 CFR 807.92(a)(6)*

Table 1 provides a side-by-side comparison of descriptive characteristics for the WowGoHealth, Model GSH-BGM902 and its legally marketed predicated device, the SuperCheck Plus, Model 5228-S (K141351).

TABLE 1 PREDICATE COMPARISON

Item	Predicate device	Proposed Devices
	SuperCheck Plus ,Model 5228-S (K141351)	**WowGoHealth, Model GSH-BGM902**
Similarity		
Intended use	The SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S) is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips or forearm. The SuperCheck Blood Glucose Monitoring System (Model 5228-S) is intended to be used by a single person and should not be shared. The SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S) is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in Monitoring the effectiveness of a diabetes control program. The SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S) should not be used for the diagnosis of or screening of diabetes or for	Same as predicate

	neonatal use. Alternative site testing should be done only during steady state times (when glucose is not changing rapidly). The SuperCheck Plus Test Strips are for use with the SuperCheck Plus Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood drawn from the fingertips or forearm. The SuperCheck Plus Control Solutions are for use with the SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S) as a quality control check to verify that the meter and test strips are working together properly.	
Over the Counter use	Yes	Same as predicate
Test strip chemical components	- FAD-Glucose Dehydrogenase (Aspergillus Oryzae) 9.1% - Potassium Ferricyanide 61.7% - Non-reactives 29.2%	Same as predicate
Measurement principle	Amperometric, FAD- glucose dehydrogenase	Same as predicate
Test range	20~600mg/dL	Same as predicate
Hematocrit	20~60%	Same as predicate
Operating conditions	10~40℃(50~104℉) 20~80%RH(non-condensing)	Same as predicate
Strip storage condition	2~30℃(35.6~86℉), below 80%RH	Same as predicate
Test time	5 sec	Same as predicate
Sample volume	1.1 uL	Same as predicate
Test sample	Finger, Forearm(AST site)	Same as predicate
Memory feature	500 measurements	Same as predicate
Day Average	7-,14-,28-,60-,90-day average glucose result	Same as predicate
Alarm	Beeping sound and/or error messages in LCD display	Same as predicate
Test strip calibration	No code strip is needed. The meter and the test strip should have the same reference number printed on the meter box and on the strip box and vial. The meter also displays reference number when inserting the test strip.	Same as predicate
Power supply	Two AAA batteries	Same as predicate
Dimension	100mm(L)*50mm(W)*20mm(H)	Same as predicate
Difference		
Control test flag	**"C"**	**"cotr"**
Data download function	Optional; via RS232 cable	Bluetooth mediated data transmission functionality; the meter has the capability to wirelessly transfer the latest test result to an APP run on a mobile

		device every time when a test is performed successfully and while the test trip is not removed from the meter.
Housing color	Black	White

Summary of design control activities/testing: *21 CFR 807.92(b)(1)*

The WowGoHealth, Model GSH-BGM902 was developed and documented within Biotest Medical Corporation's design control procedures in compliance with 21 CFR 820.30, as with the cleared SuperCheck Plus, Model 5228-S (K141351). We believe that the modifications to the device did not necessitate any new requirements for review and testing above those of the predicate product for except the usability study on the modified device's Bluetooth mediated data transmission functionality and the required bench study on the modified device's robustness to the cleaning and disinfection procedure cleared in SuperCheck Plus, Model 5228-S (K141351) after multiple cleaning and disinfection cycles. In addition, the safety and reliability testing, EMC testing, and FCC testing were adequately executed in the qualified outsourced labs using the protocols following applicable CDRH guidelines and related standards.

The risk analysis and verification and validation activities conducted are described below.

- ✓ **Risk Analysis:**

The risk analysis was conducted in accordance with the most updated EN ISO 14971 standard, which specifies the process for identifying hazards, estimating and evaluating associated risks, controlling the risks, and Monitoring the effectives of the controls.

All the risks for the identified potential hazards caused by the proposed device modifications were identified and evaluated for severity and occurrence probability. Controls were identified and, where risks were deemed unacceptable, mitigations were identified and implemented. Verification and validation testing showed the risk control to be acceptable. None of the proposed modifications to the SuperCheck Plus, Model 5228-S (K141351) presented unacceptable risks or raised new issues regarding the safety and/or effectiveness of the device, evidenced by the device's risk management summary report.

- ✓ **Verification and Validation Activities:**

Verification and Validation (V&V) activities were identified by assessment of their impact of the modifications, per the risk analysis in the device's risk management summary report. The analyses revealed that the modifications required similar V&V testing to the predicate SuperCheck Plus device, with similar acceptance criteria, as testing revealed no significant additional risk from the modifications. Testing was performed to establish that design outputs met pre-established design inputs as per design specifications (verification), specifically for the Bluetooth mediated data transmission functionality feature. Design validation ensured that the design meets user needs, and validation activities were

conducted as necessary (per 21 CFR820.30). The design change verification and validation activities for all the changes, including software-related changes are described in the Software V&V report in this submission. All the documents, including test reports, referenced are on file at Biotest Medical Corporation.

Conclusions: *21 CFR 807.92(b) (3)*

The modified WowGoHealth, Model GSH-BGM902 has the same intended use and fundamental scientific technology as the previous version of the device, which received 510(k) clearance K141351).

Modifications to the cleared device include reposition of the control test flag ("cotr") on meter display, Bluetooth mediated data transmission functionality to replace the original RS232cable, and the meter's housing color change. The modifications maintain the integrity of the SuperCheck Plus, Model 5228-S (K141351) as described in the original clearance in terms of the intended use of the device (i.e., the quantitative measurement of glucose in capillary blood), and the fundamental scientific technology employed. For the reason outlined above, the WowGoHealth, Model GSH-BGM902 is eligible for Special 510(k) in accordance with the relevant FDA guidance.

Biotest Medical Corporation has conducted a risk analysis and has performed the necessary verification and validation activities to demonstrate that the design outputs of the modified device meet the design requirements.

In summary, the WowGoHealth, Model GSH-BGM902 described in this submission is substantially equivalent to the predicate device.