BIOTEST MEDICAL CORPORATION
FRED LEE
ENGINEERING/REGULATORY MANAGER
NO. 3-2, CHIEN-KUO RD., TEPZ TANTZU DIST.
TAICHUNG 42760, TAIWAN

Re: K171822
Trade/Device Name: NuvoMed Wireless Blood Glucose Monitoring System
(Model BGM-6/0352)
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW
Dated: August 17, 2017
Received: August 21, 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
Indications for Use

NuvoMed Wireless Blood Glucose Monitoring System (Model BGM-6/0352)

The NuvoMed Wireless Blood Glucose Monitoring System (Model BGM-6/0352) consists of the NuvoMed Wireless Blood Glucose Monitor and the NuvoMed Blood Glucose Test Strip. The NuvoMed Wireless Blood Glucose Monitoring System (Model BGM-6/0352) is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips or forearm. The NuvoMed Wireless Blood Glucose Monitoring System (Model BGM-6/0352) is intended to be used by a single person and should not be shared.

The NuvoMed Wireless Blood Glucose Monitoring System (Model BGM-6/0352) 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 NuvoMed Wireless Blood Glucose Monitoring System (Model BGM-6/0352) 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).
510(k) Summary

510K #: K171822

Date Prepared: September 11, 2017

510(k) Type: Special (Device Modification)

Submitter Information: 21 CFR 807.92(a)(1)
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Device Name: 21 CFR 807.92(a)(2)
   Trade/Device Name: NuvoMed Wireless Blood Glucose Monitoring System (Model BGM-6/0352)
   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)

<table>
<thead>
<tr>
<th>Device Classification Name</th>
<th>System, Test, Blood Glucose, Over The Counter</th>
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<tr>
<td>510(K) Number</td>
<td>K141351</td>
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<tr>
<td>Device Name</td>
<td>SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S)</td>
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<tr>
<td>Regulation Number</td>
<td>862.1345</td>
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<td>Date Received</td>
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Device Description: 21 CFR 807.92(a)(4)

✓ General device description:
   • Physical components of the system

The NuvoMed Wireless Blood Glucose Monitoring System (Model BGM-6/0352) is a
product kit consisting of a blood glucose meter, test strips, a lancing device, sterile lancets, instructions for use, and a carrying case. No control solution is included in the kit; however, user may purchase NuvoMed Control Solution Level 1, 2 or 3 from his/her system provider if needed. The NuvoMed Blood Glucose Meter uses NuvoMed Blood Glucose Test Strips. Neither the meter nor the test strips will work when used with any other brand of glucose products.

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.

![Appearance and Key functions of the meter](image)

- **Test strip slot** - When the strip is inserted into the slot, the meter will automatically turn on.
- **LCD Display** - Guide you through the test using symbols and simple messages.
- **M Button** - Power ON/OFF, also for memory recalling mode, please refer to manual for detailed function description.
- **C Button** - Setting mode, please refer to manual for detailed function description.
- **Battery Compartment** - Where batteries are located.
- **Ejector** - Remove used strip

Fig. 1 NuvoMed Wireless, Model BGM-6/0352 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°C).
  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 an iOS device every time when a test is performed successfully. In this operational scenario, the user needs to install an APP to his/her iOS device to receive the test result transmitted from the meter. The meter does not play any message during the data transmission, but user can check the APP on his/her iOS 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.
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.
E_8: Fail to reset date and time after installing or changing batteries in device’s “Start Up” mode.
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. 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.

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 NuvoMed Wireless, Model
BGM-6/0352 remains unchanged from the legally marketed predicate device, SuperCheck Plus, Model 5228-S (K141351).

For the proposed device device, the modifications from the cleared SuperCheck Plus, Model 5228-S (K141351), include the following:

- New PCB with new MCU (micro controller unit) providing the same excitation voltage (bias voltage applied to the test strip) and the same reaction current sensing mechanism as those of the device’s predicate (K141351).

- Change to positive display LCD and reposition of the control test flag (“cotr”) on meter display (see Fig. 3)
  The device’s LCD is changed from negative display LCD to positive display LCD. 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; for the proposed device, the control test flag (“cotr”) is used instead.

- Change to Bluetooth mediated data transmission and removal of RS232 phone jack port for cable data download to PC
  Owing to the meter’s Bluetooth mediated data transmission functionality supporting Bluetooth 4.0 and BLP, the NuvoMed Wireless, Model BGM-6/0352 has the capability to wirelessly transfer the latest test result to an APP run on an iOS device every time when a test is performed successfully. In this operational scenario, the user needs to install Samico Health APP to his/her iOS device to receive the test result transmitted from the meter. The meter does not play any message during the data transmission, but user can check the APP on his/her iOS device to confirm if the test result is received. The meter still keeps the test result in the meter.
  With this new feature, the original RS232 phone jack port for cable data download to PC is therefore removed.

- Addition of an Error message, E_8
  The proposed device requires that when users first install the batteries or every time they
replace the device’s batteries, the device (meter) will enter “Start Up” mode. Users will see an “S” in the center and the “SET” at the right upper corner of meter screen. Users must set up correct date, time and measurement unit in “Start Up” mode before they can use the meter. As a result of this new feature, an Error message, E_8 is added to indicate the state when users fail to reset date and time correctly after installing or changing batteries.

![Fig. 4 Meter display while the device enters “Start Up” mode](image)

- **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/NuvoMed Wireless, Model BGM-6/0352](image)

- **User Manual Modifications**
  Minor modifications to the NuvoMed Wireless, Model BGM-6/0352 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 NuvoMed Wireless, Model BGM-6/0352 has not changed as a result of these modifications.

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

**NuvoMed Wireless Blood Glucose Monitoring System (Model BGM-6/0352)**

The NuvoMed Wireless Blood Glucose Monitoring System (Model BGM-6/0352) consists of the NuvoMed Wireless Blood Glucose Monitor and the NuvoMed Blood Glucose Test Strip. The NuvoMed Wireless Blood Glucose Monitoring System (Model BGM-6/0352) is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips or forearm. The NuvoMed Wireless Blood Glucose Monitoring System (Model BGM-6/0352) is intended to be used by a single person and should not be shared. The NuvoMed Wireless Blood Glucose Monitoring System (Model BGM-6/0352) 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 NuvoMed Wireless Blood Glucose Monitoring System (Model BGM-6/0352) 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 NuvoMed Wireless, Model BGM-6/0352 and its legally marketed predicated device, the SuperCheck Plus, Model 5228-S (K141351).

<table>
<thead>
<tr>
<th>TABLE 1 PREDICATE COMPARISON</th>
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<tbody>
<tr>
<td><strong>Item</strong></td>
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<tr>
<td><strong>SuperCheck Plus, Model 5228-S (K141351)</strong></td>
</tr>
<tr>
<td><strong>Similarity</strong></td>
</tr>
<tr>
<td>Intended use</td>
</tr>
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</table>
The SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S) 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 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.

<table>
<thead>
<tr>
<th>Over the Counter use</th>
<th>Yes</th>
<th>Same as predicate</th>
</tr>
</thead>
</table>
| 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°C (50~104°F)  
20~80%RH(non-condensing) | Same as predicate |
| Strip storage condition | 2~30°C (35.6~86°F), 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 iOS device every time when a test is performed successfully and while the test trip is not removed from the meter.

Error messages

| E_1: The temperature is too low. | E_8: The blood sample is not sufficient. |
| E_2: The temperature is too high. | HI: The glucose level is too high. |
| E_3: Battery Low. | LO: The glucose level is too 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. | |
| | |
| | |

Housing color | Black | White

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

The NuvoMed Wireless, Model BGM-6/0352 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 effectiveness 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 modification, 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 NuvoMed Wireless, Model BGM-6/0352 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 new PCB with new MCU (micro controller unit), change to positive display LCD and reposition of the control test flag (“cotr”) on meter display, change to Bluetooth mediated data transmission and removal of RS232 phone jack port for cable data download to PC, addition of an Error message, E_8, 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 NuvoMed Wireless, Model BGM-6/0352 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 NuvoMed Wireless, Model BGM-6/0352 described in this submission is substantially equivalent to the predicate device.