SPECIAL 510(k): Device Modification
OIR Decision Summary

To: THE FILE **RE:** DOCUMENT NUMBER k171785

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device:

   SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S); K141351

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   This change was for the following item(s):

   a. A change in the name of the device from the SuperCheck Plus Blood Glucose Monitoring System (Model 5228-S) to the WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902).
   b. Reposition of the control test flag ("cotr") on meter display
   c. Replaced the RS232 cable with Bluetooth mediated data transmission functionality
   d. Change of meter's housing color from black to white.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics (including robustness of the system to repeated cleaning and disinfection), specifications and performance characteristics of the WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902).

5. A **Design Control Activities Summary** which includes:

   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.

   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

The WowGoHealth Blood Glucose Monitoring System (Model GSH-BGM902) is intended for single-patient use only. Disinfection efficacy studies described for the predicate device (SuperCheck Plus Blood Glucose Monitoring System, Model 5228-S (K141351) using Clorox Bleach Germicidal Wipes (EPA registration number 67619-12) demonstrated complete inactivation of live Hepatitis B Virus (HBV) on the materials of the meter. Robustness accuracy studies performed for the WowGoHealth Blood Glucose Monitoring System demonstrate that there was no change in performance or in the external materials of the meter after 1100 cleaning and 1100 disinfection cycles designed to simulate 3 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

This device was cleared after the FDA issued final guidance documents for prescription use blood glucose monitoring systems (BGMS) and over-the-counter use blood glucose monitoring systems (SMBG). However, the recommendations in the guidance documents were not followed for this device since the studies were performed prior to the finalization of the guidance documents.