SPECIAL 510(k): Device Modification
OIR Decision Summary

To: THE FILE **RE:** DOCUMENT NUMBER k152534

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. (For a preamendments device, a statement to this effect has been provided.)

   Medisign MM1000 Blood Glucose Monitoring System, Medisign MM1100 Blood Glucose Monitoring System, Medisign MM1200 Blood Glucose Monitoring System, Medisign MM1000 Multi Blood Glucose Monitoring System, Medisign MM1100 Multi Blood Glucose Monitoring System, Medisign MM1200 Multi Blood Glucose Monitoring System (k111456)

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 items:

   a. Changes to the meter exterior appearance: printed model name, window backside color, and button color.
   b. Addition of a wireless data transporting feature with Bluetooth Low Energy (BLE) capability.
   c. Moved location of MUTE icon on the meter liquid crystal display (LCD).
   d. Addition of Wireless RF Mode On icon to the meter LCD display.
   e. Addition of a glucose control solution trade name for use with Smart Diabetes Bluetooth Blood Glucose Monitoring System and Smart Diabetes Bluetooth Pro Blood Glucose Monitoring System: Smart Diabetes Glucose Control Solution
   f. Addition of two new system trade names: Smart Diabetes Bluetooth Blood Glucose Monitoring System and Smart Diabetes Bluetooth Pro Blood Glucose Monitoring System
   g. Addition of 'BT' to each of the existing system trade names to read:
      Medisign MM1000 BT Blood Glucose Monitoring System
      Medisign MM1100 BT Blood Glucose Monitoring System
      Medisign MM1200 BT Blood Glucose Monitoring System
      Medisign MM 1000 BT MULTI Blood Glucose Monitoring System
      Medisign MM 1100 BT MULTI Blood Glucose Monitoring System
      Medisign MM 1200 BT MULTI Blood Glucose Monitoring System

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and specifications.

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 Medisign MM1000 BT, MM1100 BT, MM1200 BT Blood Glucose Monitoring Systems and the Smart Diabetes Bluetooth Blood Glucose Monitoring System are intended for single-patient use only and the Medisign MM 1000 BT MULTI, MM 1100 BT MULTI and MM 1200 BT MULTI Blood Glucose Monitoring Systems and the Smart Diabetes Bluetooth Pro Blood Glucose Monitoring System are intended for multiple-patient use in a professional healthcare setting. Disinfection efficacy studies were performed by an outside commercial testing laboratory and demonstrated complete inactivation of Hepatitis B Virus (HBV) with the chosen disinfectant, CaviWipes Disinfecting Towelettes (EPA Registration No.: 46781-8). Robustness studies were also performed that demonstrated that there was no change in performance or the external materials of the meter after 11,000 cleanings and 11,000 disinfection steps with CaviWipes Disinfecting Towelettes. The robustness studies were designed to simulate 3 years of multiple-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 submission was received prior to the finalization of the guidance documents.