SPECIAL 510(k): Device Modification
OIR Review Summary

To: THE FILE **RE:** DOCUMENT NUMBER K143750

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.) **MEG-2B Blood Glucose Monitoring System/ MEG-2B Pro Blood Glucose Monitoring System (K120448)**
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:

   1. **Adding silver paint (ABS Chimei 709) to the meter housing**
   2. **Changing the polycarbonate material for the LCD cover.**
   3. **Adding three new agents for cleaning and disinfection: Clorox Bleach Germicidal Wipes, Medline MicroKill Bleach Germicidal Bleach Wipes, Medline Micro-Kill+ Disinfection, Deodorizing, Cleaning Wipes with Alcohol.**
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use and physical characteristics.
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 (**Failure Mode and Effect 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.

Infection Control Studies: The MEG-2B Blood Glucose Monitoring System is intended for single patient use and the MEG-2B Pro Blood Glucose Monitoring System is intended for multiple-patient use. Disinfection efficacy testing was conducted by outside testing facilities and demonstrated complete inactivation of hepatitis B virus (HBV) or elimination of Hepatitis B surface antigen (HbsAg) with the following disinfectants: Dispatch Hospital Cleaner Disinfectant Towels with Bleach (EPA registration # 56392-8), Clorox Germicidal Wipes (EPA registration # 67619-12), Medline MicroKill Bleach Germicidal Bleach Wipes (EPA registration # 69687-1-37549), and Medline Micro-Kill+ Disinfection, Deodorizing, Cleaning Wipes with Alcohol (EPA registration # 59894-10-37549). Robustness studies were performed by the sponsor demonstrating that there were no changes in the performance or external materials of the meter after 10,950 cleanings and 10,950 disinfection cycles with the Dispatch Hospital Cleaner

Disinfectant Towels with Bleach (EPA registration # 56392-8), and three additional disinfectants that were evaluated in the same manner in this submission: Clorox Germicidal Wipes (EPA registration # 67619-12), Medline MicroKill Bleach Germicidal Bleach Wipes (EPA registration # 69687-1-37549), and Medline Micro-Kill+ Disinfection, Deodorizing, Cleaning Wipes with Alcohol (EPA registration # 59894-10-37549). 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.