SPECIAL 510(k): Device Modification
OIR Decision Summary

To: THE FILE **RE:** DOCUMENT NUMBER K142689

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.) **GAL-1E Blood Glucose Monitoring System and GAL-1E Multi Blood Glucose Monitoring System, k113547**

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:

   i. Re-design of the device appearance: moving the strip reader location from the top of the device to the bottom, and eliminating a strip eject button from the device design.
   ii. Adding functionality that allows blood glucose data to be transferred to a personal computer
   iii. Design changes to the device circuit board.
   iv. Adding new disinfecting agents into the instructions for use.

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

Infection Control Studies:

GAL-1F Blood Glucose Meter
The device system is intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) or elimination of Hepatitis B surface antigen (HbsAg) with the chosen disinfecting agents, Dispatch Hospital Cleaner Disinfectant Towels with Bleach (EPA Registration # 56392-8), Clorox Bleach 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 also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter and lancing device after 1,825 cleanings and 1,825 disinfection steps with the Dispatch Hospital Cleaner Disinfectant Towels with Bleach, Clorox Bleach Germicidal Wipes, Medline Microkill Bleach Germicidal Bleach Wipes and Medline Micro-Kill+ Disinfection, Deodorizing, Cleaning Wipes with Alcohol. The robustness studies were designed to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

GAL-1F Multi Blood Glucose Meter
The device system is intended for use in multiple patients with single use, auto-disabling lancing devices. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing demonstrating complete inactivation of hepatitis B virus (HBV) or elimination of Hepatitis B surface antigen (HbsAg) with the chosen disinfecting agents, Dispatch Hospital Cleaner Disinfectant Towels with Bleach (EPA Registration # 56392-8), Clorox Bleach 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 also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter and lancing device after 10,950 cleanings and 10,950 disinfection steps with the Dispatch Hospital Cleaner Disinfectant Towels with Bleach, Clorox Bleach Germicidal Wipes, Medline Microkill Bleach Germicidal Bleach Wipes and Medline Micro-Kill+ Disinfection, Deodorizing, Cleaning Wipes with Alcohol. 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.