SPECIAL 510(k): Device Modification
OIVD Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER: **k133647**

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.) **EG V1(BL) Self-Monitoring Glucose Test System and EG V1 Pro Self-Monitoring Glucose Test System k101037.**

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:
   A. The physical appearance of the meter has changed. The dimensions of the meter were modified from 3.5 x 2.1 x 0.9 inches (2.15 oz. w/o batteries) to 3.63 x 1.96 x 0.91 inches (1.57 oz. w/o batteries).
   B. The trade names of the systems have changed from EGV1(BL) Self-Monitoring Glucose Test System and EGV1 Pro Self-Monitoring Glucose Test System to EMV3.1 Self-Monitoring Blood Glucose System and EMV3.1 Pro Blood Glucose System, respectively.
   C. The trade name of the control solution has changed from EG Glucose Control Solution to EMV3.1 Glucose Control Solution.
   D. The trade name of the blood glucose test strips has changed from EG Blood Glucose Test Strips and EG Pro Blood Glucose Test Strips to EMV3.1 Blood Glucose Test Strips and EMV3.1 Pro Blood Glucose Test Strips, respectively.
   E. Power type changed from 2 x CR2032 Lithium to 2 x AAA Alkaline Battery (1.5 volt).
   F. Addition of a voice function.
   G. Addition of one power button on the front-side of the meter.
   H. Label the right arrow function button as "C" and left arrow function button as "M". This modification includes minor software changes.
   I. Labeling was modified to reflect the changes to the device.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, analytes and performance 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.
   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
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

6. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

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 risk analysis for the modifications identified software verification, validation and testing (W&T) to perform and result meet the predetermined acceptance criteria.

The device system is intended for single patient home use (EMV 3.1 Self-Monitoring Blood Glucose System) and multiple patient use in a professional healthcare setting (EMV3.1 Pro Blood Glucose System). Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial laboratory testing service demonstrating complete inactivation of hepatitis B Virus (HBV) with PDI Super SANI-CLOTH® Germicidal disposable wipes (EPA Reg. No: 9480-4). The sponsor also conducted robustness studies and demonstrated that there was no change in performance or in the external materials of the meter (for single patient use only) after 10,000 cleaning and disinfecting cycles to support 4 years of single-patient use and 3 years of multiple-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.