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

To: THE FILE **RE:** DOCUMENT NUMBER: **k112901**

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 to 3.8 x 2.0 x 0.6 inches.
   B. The trade name of the meter has changed from EG V1(BL) Self Monitoring Glucose Test System and EG V1 Pro Self Monitoring Glucose Test System to EME Self Monitoring Blood Glucose System and EME Pro Self Monitoring Blood Glucose System respectively.
   C. Power type changed from 2 x CR2032 Lithium to 2 x AAA Lithium Battery.
   D. Addition of a strip eject button on the side of the meter.

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.

Reviewer's Comments:

The device is intended for single patient home use (EME Self Monitoring Blood Glucose System) and multiple patient use in a professional healthcare setting (EME Pro Self Monitoring Blood Glucose System). Disinfection efficacy studies were performed on the materials comprising the meter and lancing device by an outside commercial laboratory testing services 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 and lancing device (for single patient use only) after 20,000 disinfecting cycles for the meter and 14,600 disinfection cycles for the lancing device which represents 4 years of cleaning after each use (up to 9 times per day) and disinfection once a week by lay users. The meter (EME Pro Self Monitoring Blood Glucose System) was validated for multiple-patient use with 20,000 disinfecting cycles (each cycle tested consisted of one pre-clean wipe and one disinfecting wipe) to represent 3 years of cleaning and disinfection after each use.