

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

**To:** THE FILE

**RE:** DOCUMENT NUMBER K133537

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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:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. **k101037, EG V1 (BL) Self Monitoring Blood Glucose System and EG V1 Pro Self Monitoring Blood Glucose System.**
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. Physical appearance including size and weight. The size changed from 3.5 x 2.1 x 0.9 inches to 3.8 x 2.0 x 0.6 inches, and the weight changed from 2.05 oz. to 1.38 oz. w/o batteries.
  - B. The outer casing buttons are changed from left and right buttons to left, middle, and right buttons.
  - C. Software modification for inclusion of a deletion of test results function; removal of hypoglycemia and hyperglycemia alarms, and calculation of average pre-meal and post-meal glucose concentrations.
  - D. Change of the battery type from Lithium to Alkaline.
  - E. Change of the model names from EG V1(BL) Self Monitoring Glucose Test System, to EGV1.1 Self Monitoring Blood Glucose system and EG V1 Pro Self Monitoring Glucose Test System to EGV1.1 Pro Monitoring Blood Glucose system
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and cleaning and disinfection robustness study.
  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 EGV1.1 Self Monitoring Blood Glucose System and EGV1.1 Pro Monitoring Blood Glucose System are intended for single- and multiple-patient use, respectively. 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) with the chosen disinfectant, PDI Super Sani-Cloth Germicidal Disposable Wipe (EPA Registration # 9480-4). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 10,950 cleaning and disinfection cycles with the PDI Super Sani-Cloth Germicidal Disposable wipes. The robustness studies were designed to simulate 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.