

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

To: THE FILE

RE: DOCUMENT NUMBER: **k112272**

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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 Test 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.
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.
  - B. The button functions were changed and two additional buttons were added to the side of the meter.
  - C. The name of two devices has changed from (1) "EG V1 (BL)" to "EM44" and (2) "EG V1 Pro" to "EM44 Pro".
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, performance characteristics and Flesch-Kincaid readability assessment.
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 devices are intended for single (EM44) and multiple patient use (EM44 Pro). **PDI Super Sani-Cloth Germicidal Disposable Wipe** with EPA registration # 9480-4 was validated demonstrating complete inactivation of live Hepatitis B virus for use with the single and multi-patient use blood glucose meters and the lancing device that will be used with the single-patient use blood glucose monitoring system. For multi-patient use, the sponsor demonstrated that there was no change in performance or in the external materials of the meter after 10,000 cleaning and 10,000 disinfection cycles designed to simulate cleaning

and disinfection 9 times a day, over 3 years of device use. For single-patient use, the sponsor demonstrated that there was no change in performance or in the external materials of the meter after 10,000 cleaning and 10,000 disinfection cycles designed to simulate 4 cleaning times a day and 1 disinfection time per week, over 4 years of device use. The sponsor also demonstrated that there was no change in performance or in the external materials of the lancing device after 7,200 cleaning and 7,200 disinfection cycles designed to simulate 4 cleaning times a day and 1 disinfection time per week, over 4 years of device use for single-patient use. In addition, the sponsor provided a risk analysis specific to the potential harm due to infection. Labeling has been reviewed for adequate instructions in validated cleaning and disinfection procedures.