

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

To: THE FILE

RE: DOCUMENT NUMBER

k133389

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.

EG V1 (BL) Self-Monitoring Glucose Test System, EG V1 Pro Self-Monitoring Glucose Test System cleared under 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:

- To add two additional names to the cleared system: EM40 Self-Monitoring Blood Glucose System, EM40 Pro Self-Monitoring Blood Glucose System
 - The predicate device has two front buttons while the modified device has one front button and one up/down side button
 - The predicate device is composed of ABS (Acrylonitrile Butadiene Styrene), PC (polycarbonate), and Rubber/TPE (Thermoplastic Elastomer) while the modified device is composed of PC only
 - The software was modified to accommodate the new buttons
 - The printed circuit board was modified to accommodate the new buttons
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, and physical 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 sponsor's previously cleared device.

The devices are intended for single-patient (EM40) or multiple-patient (EM40 Pro) use. PDI SANI-CLOTH Germicidal disposable wipes (EPA Reg. No: 9480-4) were validated through disinfection efficacy studies demonstrating complete inactivation of hepatitis B (HBV) virus using materials comprising the meter. Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or in the external materials of the meter after 10,950 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate three years of multiple-patient use. This testing was also adequate to simulate 4 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.