

## SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

### I Background Information:

#### A 510(k) Number

K190189

#### B Applicant

EPS Bio Technology Corp.

#### C Proprietary and Established Names

MDT2 BLE Self-Monitoring Blood Glucose System

#### D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NBW	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry

### II Review Summary:

This 510(k) submission contains information/data on modifications made to the submitter's own CLASS II device requiring 510(k). The following items are present and acceptable.

1. The name and 510(k) number of the SUBMITTER'S previously cleared device EM40 Self-Monitoring Blood Glucose System (k133389).
2. Submitter's statement that the **INDICATIONS FOR USE/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).

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:**

- Change in test strip to be recognized by the candidate meter and turn on the meter when inserted.
- Addition of Bluetooth functionality to the meter.
- Removed meter glucose result averaging function.
- Addition of button to reset the meter.
- Move the test strip port from the top to the bottom of the meter.
- Change display icon from the fingertip symbol to a drop of blood.
- Addition of before meal, after meal, control test, AM and PM icons.
- Buttons changed from one front button and two side buttons to two front buttons
- Meter dimensions and weight changed from 86 X 47 X 13.8 mm and 43 grams to 98 X 49.9 X 11.3 mm and 49 grams without batteries.
- Meter shell color changed from black to white
- System name changed from EM40 Self-Monitoring Blood Glucose System to MDT2 BLE Self-Monitoring Blood Glucose System

Comparison Information (i.e., similarities and differences) to the submitter's legally marketed predicate device including, labeling, intended use, and physical characteristics.

3. 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.

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.

This MDT2 BLE Self-Monitoring Blood Glucose System is intended for single-patient use only. Disinfection efficacy studies were performed on the external materials comprising the meter demonstrating complete activation of hepatitis B virus (HBV) with the chosen disinfectant, PDI Sani-Cloth Germicidal wipes (EPS Registration number 9480-4). 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 8,760 cleaning and 208 disinfection wipes. Robustness studies were designed to support 4 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.