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

To: THE FILE **RE:** DOCUMENT NUMBER: **k120042**

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) for the TD-4268 Blood Glucose Monitoring System and TD-4268 Multi Blood Glucose Monitoring System:

1. The name and 510(k) number of SUBMITTER'S previously cleared device: TD-4239 Blood Glucose Monitoring System and TD-4239 Multi Blood Glucose Monitoring System (k101635)

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:
   - Change to meter shell colors and shape
   - Size and weight of meter from 95mm x 49mm x14mm (LxWxH) and 42g to 95mm x 55mm x 20 mm and 76.2g
   - Button configuration
   - Addition of backlight
   - Power source from one 3V CR2032 lithium battery to two 1.5V AAA batteries
   - Increased memory from 400 to 1000 measurements

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 previously cleared device.

The device is intended for single-patient (TD-4268 Blood Glucose Monitoring System) or multiple-patient use (TD-4268 Multi Blood Glucose Monitoring System). Disinfection efficacy studies were performed on the materials comprising the meters by an outside commercial testing service demonstrating complete inactivation of hepatitis B virus (HBV) with Micro-Kill Plus™ disposable wipes (EPA Reg. No: 59894-10-37549). The sponsor also demonstrated that there was no change in performance or in the external materials of the meter after 10,000 cleaning and disinfection cycles designed to simulate 3 years of multiple-patient use by healthcare professionals and 5 years of single-patient use. Labeling has been reviewed for adequate instructions for the validated cleaning and disinfection procedures.