SPECIAL 510(k): Device Modification
OIR Decision Memorandum

To: THE FILE **RE:** k173511

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: k100322, TD-4277 Blood Glucose Monitoring System, Model TD-4277.

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:

   - The user interface was changed by adding a touchscreen and eliminating buttons.
   - Addition of ability for the user to tag results, for example, before breakfast, after breakfast, before lunch etc.
   - The error code displays were changed to short error messages and additional messages were added.
   - In addition to the default reporting unit mg/dL, an option was added for reporting mmol/L.
   - In addition to the default English language, an option was added for Spanish.
   - The transmission function of the mini USB connection was removed and it was changed to a mico USB for charging only.
   - The timeout function was changed from 180 seconds of no activity to standby after 1 minute and power off after 10 minutes.
   - The EEprom memory type was changed to FLASH memory.
   - The 2x AAA batteries were changed to one rechargable Li-polymer battery.
   - The name was changed to ActiveCare TD-4121 Blood Glucose Monitoring System.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and specifications.
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

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 ActiveCare TD-4121 Blood Glucose Monitoring System is intended for single-patient home use only. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of viral hepatitis B virus (HBV) with the chosen disinfectant, Micro-Kill+. Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 260 cleaning and disinfection cycles designed to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.