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

To: THE FILE **RE:** DOCUMENT NUMBER: k121224

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 for the **Genesis Health Technologies Blood Glucose Monitoring System, model TD-4123**:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.
   Taidoc Technology Corporation, U-RIGHT TD-4252 blood glucose monitoring system (k101631)

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:

   A. Physical appearance including size and weight. The size changed from 89.6(L) x 53.8 (W) x 16.1 (H)mm to 98.5(L) x 58(W) x 15.5(H)mm, and the weight changed from 40.6g to 51.4g (without battery).
   B. The outer casing buttons are changed to main button, up button, down button and set button (from M button, C button and set button in the outer casing of the predicate device).
   C. Software modification to include the AC and PC measuring mode, the data analysis mode, the memory record review mode, Test Light Indicator, and the back light function. The warning message for ketone is removed. QC test results are stored and can be reviewed in memory record review mode. Data averaging function is removed.
   D. Battery changed to a rechargeable 3.7V lithium polymer battery (from a lithium CR2032 battery in the predicate device).
   E. A USB port for battery recharging is included in the modified device.
   F. Glucose measurement unit set to mg/dL only.
   G. Labeling was modified to reflect the changes to the device
   H. Trade name of the device (meter and test strips) has changed from U-Right TD-4252 blood glucose monitoring system to the Genesis Health Technologies Blood Glucose Monitoring System, model TD-4123.
   I. The Genesis Health Technologies Control solutions are to be used in place of the FORA control solutions with the Genesis Health Technologies Blood Glucose Monitoring System, model TD-4123.

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

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 Genesis Health Technologies Blood Glucose Monitoring System, model TD-4123 is intended for single patient home use. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with Microkill Plus Wipes (EPA Reg. No: 59894-10-37549). The sponsor has demonstrated that there is no change in performance or in the external materials of the meter after 5000 pre-cleaning/disinfection cycles (each pre-cleaning/disinfection cycle includes one pre-cleaning and one disinfection wipe, adding up to a total of 10,000 wipes) designed to simulate two pre-cleaning/disinfection cycles per day for 5 years of device use. Labeling has been reviewed for adequate instructions for validated cleaning and disinfection procedures.