

SPECIAL 510(k): Device Modification
OIR Decision Summary

To: THE FILE

RE: DOCUMENT NUMBER K151100

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. (For a preamendments device, a statement to this effect has been provided.) **U-RIGHT TD-4227 No Coding Blood Glucose Monitoring System (K090188)**
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. Changing the meter dimensions from 96mm(L) x 45 mm (W)x 23 mm (H) to 89mm(L) x 52 mm (W)x 17 mm (H). The thickness of the housing has also been reduced, resulting in a decrease in the weight of the meter from 71 g to 47 g (without the battery).
 - B. Additional (optional) user modes have been added to categorize if results are obtained before or after meals.
 - C. Four (optional) daily alarms have been added.
 - D. Power source has been changed from two 1.5 V AAA batteries to one 1.5 V AAA battery.
 - E. The open vial stability claim for the test strips is increased from three months to six months.
 - F. Calf and thigh are removed as alternative testing sites.
 - G. Speaking function has been removed.
 - H. Incorporating new validated cleaning and disinfection protocols into the labeling..
 - I. The name of the device was changed from the U-RIGHT TD-4227 No Coding Blood Glucose Monitoring System to the U-RIGHT TD-4116 Blood Glucose Monitoring System and U-RIGHT TD-4116 Pro Blood Glucose Monitoring System.
 - J. The labeling has been changed to reflect the other changes to the system.
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

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 modifications 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.

Infection Control Studies: The U-RIGHT TD-4116 Blood Glucose Monitoring System is intended for single patient use and the U-RIGHT TD-4116 Pro Blood Glucose Monitoring System is intended for multiple-patient use. Disinfection efficacy testing was conducted by outside testing facilities and demonstrated complete inactivation of hepatitis B virus (HBV) with Micro-Kill+ (Micro-Kill Plus) Professional Disinfecting Wipes (EPA registration number 59894-10-37549). Robustness studies were performed by the sponsor demonstrating that there were no changes in the performance or external materials of the meter after 10,950 cycles of cleaning and disinfection with Micro-Kill+ (Micro-Kill Plus) Professional Disinfecting Wipes. The robustness studies were designed to simulate 3 years of multiple patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.