

SPECIAL 510(k): Device Modification ODE Review Summary

To: THE FILE

RE: DOCUMENT NUMBER K140150

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. GL GOODLIFE SERIES BLOOD GLUCOSE MONITORING SYSTEM (k113307), which includes:

- GoodLife AC-300 Blood Glucose Monitoring System
- GoodLife AC-301 Blood Glucose Monitoring System
- GoodLife AC-302 Blood Glucose Monitoring System
- GoodLife AC-303 Blood Glucose Monitoring System
- GoodLife AC-304 Blood Glucose Monitoring System
- GoodLife AC-305 Blood Glucose Monitoring System
- GoodLife AC-300 Professional Blood Glucose Monitoring System
- GoodLife AC-301 Professional Blood Glucose Monitoring System
- GoodLife AC-302 Professional Blood Glucose Monitoring System
- GoodLife AC-303 Professional Blood Glucose Monitoring System
- GoodLife AC-304 Professional Blood Glucose Monitoring System
- GoodLife AC-305 Professional Blood Glucose Monitoring System

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. Addition of a Near Field Communication (NFC) module for wireless data transmission.
 - B. Addition of the NFC symbol to the S/N label of meters.
 - C. Change to the amount of foil-packed strips available: Added 15 strip and 100 strip packages to the existing 50 strip package format.
 - D. Change to the bag size and the label size of foil packed strip package to accommodate the new 15 and 100 strip package formats.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and wireless data transmission
 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 device.

The GoodLife AC-300 Blood Glucose Monitoring System, GoodLife AC-301 Blood Glucose Monitoring System, GoodLife AC-302 Blood Glucose Monitoring System, GoodLife AC-303 Blood Glucose Monitoring System, GoodLife AC-304 Blood Glucose Monitoring System, GoodLife AC-305 Blood Glucose Monitoring System are intended for single-patient use. The GoodLife AC-300 Professional Blood Glucose Monitoring System, GoodLife AC-301 Professional Blood Glucose Monitoring System, GoodLife AC-302 Professional Blood Glucose Monitoring System, GoodLife AC-303 Professional Blood Glucose Monitoring System, GoodLife AC-304 Professional Blood Glucose Monitoring System, GoodLife AC-305 Professional Blood Glucose Monitoring System are intended for multiple patient use in a professional healthcare setting. Disinfection efficacy studies were performed for the predicate device (k113307) by an outside commercial testing laboratory and demonstrated complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Clorox Commercial Solutions® Clorox® Germicidal Wipes (EPA Registration # 67619-12). Robustness studies also performed for the predicate device demonstrated that there was no change in performance or external materials of the meters after 18,250 cleanings and 18,250 disinfection steps with Clorox Commercial Solutions® Clorox® Germicidal Wipes. The robustness studies were designed to simulate 5 years of multi-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures. There were no physical changes to the device relative to the predicate that would warrant new disinfection efficacy or robustness testing.