

SPECIAL 510(k): Device Modification OIR Review Memorandum

To: THE FILE

RE: DOCUMENT NUMBER K150274

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. **K132966, GluNEO Lite 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. Change of the system names from GluNEO Lite Professional Blood Glucose Monitoring System to GDH Professional Blood Glucose Monitoring System and GDH Professional LED Blood Glucose Monitoring System.
 - B. Change in the names of control solutions from GluNEO Lite Professional Control Solutions to GDH Professional Control Solutions.
 - C. Change in battery number from one to two batteries.
 - D. Change in the display type from a positive LCD screen to a negative LCD screen with backlighting for the GDH Professional LED Blood Glucose Monitoring System.
 - E. Change in the physical appearance including color, size and weight.
 - F. Changes to the appearance of before meal and after meal icons, and to the location of these and other icons on the display screen.
 - G. Inclusion of an LED light for illumination of the sample test port (GDH Professional LED Blood Glucose Monitoring System models only).
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics (dimensions, weight) , and specifications were provided.
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 GDH Professional Blood Glucose Monitoring System and GDH Professional LED Professional Blood Glucose Monitoring System are intended for multiple-patient use. The materials of the meter for each device are identical apart from an additional LED light on the GDH Professional LED Professional Blood Glucose Monitoring System. Disinfection efficacy studies were performed on the materials comprising the GDH Professional and GDH Professional LED Blood Glucose meter by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, CaviWipes (EPA Registration # 46781-8). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 10,950 cleaning and disinfection cycles with the CaviWipes 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.