

SPECIAL 510(k): Device Modification
OIR Decision Summary

To: THE FILE

RE: DOCUMENT NUMBER K160365

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.) **K130181, GluNEO Blood Glucose Monitoring System, GluNEO 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 the following items:
 - a. Addition of Bluetooth module to the meter for wireless data transfer to mobile devices.
 - b. Change in material, color and texture of BLE Smart and BLE Smart Professional meter housing and LCD screen.
 - c. The trade name of the system has changed from GluNEO Blood Glucose Monitoring System and GluNEO Professional Blood Glucose Monitoring System to the BLE Smart Blood Glucose Monitoring System and BLE Smart Professional Blood Glucose Monitoring System.
 - d. The trade name of the glucose control solution has changed from GluNEO Glucose Control Solution and GluNEO Glucose Control Solution to the BLE Smart Blood Glucose Control Solutions and BLE Smart Professional Blood Glucose Control Solutions.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and device performance 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 BLE Smart Blood Glucose Monitoring Meter is intended for single patient use only. The BLE Smart Professional Blood Glucose Monitoring Meter is intended for multiple-patient use in professional healthcare settings. Disinfection efficacy studies were performed on the material comprising the meter by an outside commercial testing laboratory demonstrating complete

inactivation of duck hepatitis B virus (surrogate virus for human hepatitis B virus) with CaviWipes (EPA Registration Number: 46781-8). Robustness studies were also performed separately for the CaviWipes demonstrating that there was no change in performance or external materials of the meter following 10,950 cleaning and disinfection cycles. The robustness studies were designed to simulate three years of multiple-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.