

SPECIAL 510(k): Device Modification OIR Review Summary

To: THE FILE

RE: DOCUMENT NUMBER K 142928

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:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device: **FreeStyle Precision Neo Blood Glucose Monitoring System (k140371)**.
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 addition of a user settable hypoglycemic (hypo) and hyperglycemic (hyper) indicator feature for the FreeStyle Precision Neo Blood Glucose Monitoring System.

The Sponsor claims that the above changes in new device will not influence substantial equivalence (SE) to its predicate device.

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 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 FreeStyle Precision Neo Blood Glucose Monitoring System is intended for single-patient use only. Disinfection efficacy studies were previously performed in the 510(k) k140371. Robustness studies were also performed previously (k140371) by the sponsor demonstrating that there was no change in performance or external materials for each of the meters after 522 cleaning and 522 disinfection steps designed to simulate 2 cleaning and disinfection cycles each week for 5 years of single-patient use of using the Clorox Healthcare Bleach Germicidal wipes. The modification (addition of a user settable hypoglycemic (hypo) and hyperglycemic (hyper) indicator) does not affect the exterior

features of the meter, therefore new cleaning/disinfection and robustness studies were not necessary. The labeling adequately notifies the user to the limitations of the device and proper interpretation of the test results.