

SPECIAL 510(k): Device Modification OIR Review Summary

To: THE FILE

RE: DOCUMENT NUMBER K150332

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.) **k092602, FreeStyle Lite 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: Incorporate validated cleaning and disinfection procedures into the labeling for the FreeStyle Lite Blood Glucose Monitoring System.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use and physical characteristics. **Studies performed include disinfection efficacy study to show viral elimination effectiveness and meter robustness studies.**
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 Lite Blood Glucose Monitoring System is intended for single-patient use. Disinfection efficacy of the Clorox Healthcare Bleach Germicidal Wipes (EPA #67619-12) was validated using materials from the meters demonstrating complete inactivation of duck hepatitis B virus (HBV). The sponsor also performed robustness studies demonstrating that there was no change in performance or in the materials of the FreeStyle Lite Blood Glucose Meter after 1044 cleaning and 1044 disinfection cycles (4 cycles per week for 5 years) designed to simulate five years use life of the device. However, the sponsor has provided a risk management report which includes a risk analysis for 522 cleaning and 522 disinfection cycles to claim 2 cleaning and disinfection cycles for a 5 years use life of the device in the labeling. The labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.