# SPECIAL 510(k): Device Modification
# OIR Decision Summary

**To:** THE FILE **RE:** DOCUMENT NUMBER: k153238

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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, FreeStyle InsuLinx Blood Glucose Monitoring System (k120568). 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).
2. 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 changing the wipes used for cleaning and disinfection from Dispatch hospital cleaner disinfectant towels with bleach, EPA # 56392-8 to Clorox healthcare bleach germicidal wipes, EPA #67619-2.
3. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and performance characteristics Studies performed include disinfection robustness testing to verify that the meter meets the acceptance criteria which is to pass the tests to stay functional after cleaning and disinfecting. In addition, disinfection efficacy testing was done to ensure that the meter meets the disinfection requirements.
4. 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 FreeStyle InsuLinx Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples for a single person. 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 InsuLinx Blood Glucose Monitoring System after 522 cleaning and 522 disinfection cycles (1 cycle per week for 5 years) designed to simulate five years use life of the device. The labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.