

**SPECIAL 510(k): Device Modification
OIR Review Summary**

To: THE FILE

RE: DOCUMENT NUMBER K152442

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): **Freestyle Freedom Blood Glucose Monitoring System**.

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.) **FreeStyle Blood Glucose Test Strips (K092638)**
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:

Incorporating new validated cleaning and disinfection procedures into the labeling of the FreeStyle Freedom Blood Glucose Monitoring System to include: Clorox Healthcare Bleach Germicidal Wipes (67619-12).

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, and physical characteristics (including efficacy of cleaning and disinfection agents on the materials of the meter and robustness of the system to repeated cleaning and disinfection).
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.

Infection Control Studies:

The Freestyle Freedom Blood Glucose Monitoring system is intended for single-patient use only. Disinfection efficacy studies were performed on materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of Duck hepatitis B virus (DHBV) with the chosen disinfecting agent, Clorox Bleach Germicidal Wipes (EPA Registration #67619-12). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 1044 cleaning and disinfection cycles with Clorox Bleach Germicidal Wipes (EPA Registration #67619-12). The robustness studies were designed to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.