SPECIAL 510(k): Device Modification
OIR Decision Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER K150942

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): **Contour Next USB 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.): **Contour Next USB Blood Glucose Monitoring System (K121087).**
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 addition of mechanisms to detect errors that might occur during use of the device. Specifically, the change includes the addition of error condition checks related to test strip degradation, improperly mixed control solutions, and sample perturbation during a test.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and software functionality.
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 Contour Next USB Blood Glucose Monitoring System is intended for single-patient use only. Disinfection efficacy studies described for the predicate device (k121087, Contour Next USB Blood Glucose Monitoring System) using Clorox® Germicidal Wipes containing 0.55% sodium hypochlorite (EPA registration # 67619-12) demonstrated complete inactivation of live Hepatitis B Virus (HBV) on the materials of the meter. Studies described for the predicate device also demonstrate that there was no change in performance or in the external materials of the meter after 260 cleaning and disinfection cycles designed to simulate cleaning and disinfection 1x per week for 5 years. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures. There were no physical changes to the device relative to the predicate that would warrant new disinfection efficacy or robustness testing.