SPECIAL 510(k): Device Modification
OIR Decision Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER K162336

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.):

   Contour Next EZ Blood Glucose Monitoring System (K130265).

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 submission is for modifications to the Contour Next EZ Blood Glucose Meter, which is a component of the Contour Next EZ Blood Glucose Monitoring System (K130265).

   This change was for the addition of mechanisms to detect errors that might occur during use of the device. Specifically, the device was modified to include the addition of error condition checks related to test strip degradation, improperly mixed control solutions, and sample perturbation during a test. Additionally, 'Q Token' parameters were added to the meter computer interface to improve communication between the meter and the data management system.

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 EZ Blood Glucose Monitoring System is intended for single-patient use only. Disinfection efficacy studies described for the predicate device (k130265 for Bayer Contour Next Blood Glucose Monitoring System) using Clorox® Germicidal Wipes (EPA registration # 67619-12) demonstrated complete inactivation of live Hepatitis B Virus (HBV) on the materials of the meter. Studies described for the predicate devices also demonstrate that there was no change in performance or in the external materials of the meter after 260 cleaning and 260 disinfection cycles (520 cleanings total) 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.

This device was cleared after the FDA issued final guidance documents for prescription use blood glucose monitoring systems (BGMS) and over-the-counter use blood glucose monitoring systems (SMBG). However, the recommendations in the guidance documents were not followed for this device since the submission was received prior to the finalization of the guidance documents.