SPECIAL 510(K): DEVICE MODIFICATION
OIR DECISION SUMMARY

510(k) Number: k181131

This 510(k) submission contains information/data on modifications made to the applicant's own class II or class I devices requiring 510(k). The following items are present and acceptable:

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1. The name and 510(k) number of the applicant's previously cleared device: Accu-Chek Guide Blood Glucose Monitoring System (k160944). (For a preamendments device, a statement to this effect has been provided.)

2. Applicant'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**.

   The changes were for the following items:

   - Removal of the target range indication, pattern detection, and meal indication features.
   - Removal of the beep associated with reminders
   - Removal of the test strip ejector and test strip port light
   - Modified the LCD display from dot matrix to fixed segment and removed the backlight
   - Reduced the number and type of meter buttons
   - Reduced the BLE pairing capability of the meter from paring with 5 devices at a time to one device
   - Change in external meter materials.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and specifications.

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 Accu-Chek Guide Me Blood Glucose Monitoring System is intended for single-patient use only. Disinfection efficacy studies were conducted on external meter materials and demonstrated complete inactiviation of hepatitis B Virus (HBV) with Super Sani-Cloth Wipes, EPA Registration No. 9480-4 . The sponsor also conducted robustness studies and demonstrated that there was no change in performance or in the external materials of the meter after 260 cleaning and disinfection cycles representing 5 years of single patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.