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

**To:** THE FILE **RE:** DOCUMENT NUMBER k170267

---

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: **BGM009 Blood Glucose Monitoring System (k141036).**

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 the following item(s)**:

   a. A change in the name of the device from the BGM009 Blood Glucose Monitoring System to the BGM009 Plus Blood Glucose Monitoring System.
   b. Removal of the voice feature that includes language and volume change settings.
   c. Replacement of the speaker to buzzer on the printed circuit board assembly (PCBA).
   d. Software has been modified:
      1. To support removal of voice feature
      2. Remove language selection function
      3. Change volume selection function to buzzer setting mode

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 BGM009 Plus Blood Glucose Monitoring System is intended for single-patient use only. Disinfection efficacy studies described for the predicate device (k141036 for BGM009 Blood Glucose Monitoring System) using Clorox Healthcare Bleach Germicidal Wipes (EPA registration number 67619-12-5813) 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 1825 cleaning and 1825 disinfection cycles (3650 cleanings total) designed to simulate cleaning and disinfection 7 times per week for 5 years. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.