SPECIAL 510(k): Device Modification
OIR Review Summary

To: THE FILE **RE:** DOCUMENT NUMBER K150052

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): **TRUE METRIX AIR Self-Monitoring Blood Glucose System and TRUE METRIX AIR PRO Professional Monitoring Blood Glucose 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.) **TRUE METRIX Self-Monitoring Blood Glucose System, TRUE METRIX PRO Professional Monitoring Blood Glucose System; K140100**

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:

   1. The name has changed from TRUE METRIX Self-Monitoring Blood Glucose System to TRUE METRIX AIR Self-Monitoring Blood Glucose System; and TRUE METRIX PRO Professional Monitoring Blood Glucose System to TRUE METRIX AIR PRO Professional Monitoring Blood Glucose System;
   2. Addition of Bluetooth® Smart for wireless test data transfer;
   3. Expanding the glucose meter memory from 500 to 1000 test results and;
   4. Providing glucose average options of 60 and 90 days in addition to the existing 7, 14, and 30 days.

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

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 (**Failure Mode and Effect 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.

There have been no changes to the surface materials of the TRUE METRIX AIR Self-Monitoring Blood Glucose System and TRUE METRIX AIR PRO Professional Monitoring Blood Glucose Systems in this submission. Validated disinfection efficacy and robustness studies were reviewed in K120989. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.