SPECIAL 510(k): Device Modification
OIR Review Summary

To: THE FILE **RE:** DOCUMENT NUMBER K151164

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): **Assure Prism multi 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.) **ACURA Plus Multi Blood Glucose Monitoring System (k131419).**

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:

   i. Incorporating validated cleaning and disinfection procedures for additional disinfectant products into the labeling of the Assure Prism multi Blood Glucose Monitoring System.
   ii. Changing the symbols on the meter buttons to use arrows instead of letters.
   iii. Changing the brand name of the device and the logo printed on the test strips; previously the device was the ACURA Plus Multi Blood Glucose Monitoring System and the test strips were printed with the logo "ACURA". The device is now named the Assure Prism multi Blood Glucose Monitoring System and the test strips are printed with the logo "ARKRAY".

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, and physical characteristics (including efficacy of cleaning and disinfection agents on the materials of the meter and robustness of the system to repeated cleaning and disinfection).

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.

Infection Control Studies: The Assure Prism Multi Blood Glucose Monitoring System is intended for multiple-patient use. Disinfection efficacy testing was conducted by outside testing facilities and demonstrated complete inactivation of hepatitis B virus (HBV) with: Clorox Germicidal Wipes (EPA registration # 67619-12), Dispatch Hospital Cleaner Disinfectant Towels with Bleach (EPA registration # 56392-8), CaviWipes 1 (EPA registration # 46781-13), and PDI Super Sani-Cloth Germicidal Disposable Wipe (EPA registration # 9480-4). Robustness studies were performed by the sponsor demonstrating

that there were no changes in the performance or external materials of the meter after 10,950 cleanings and 10,950 disinfection cycles with: Clorox Germicidal Wipes (EPA registration # 67619-12), Dispatch Hospital Cleaner Disinfectant Towels with Bleach (EPA registration # 56392-8), CaviWipes 1 (EPA registration # 46781-13), and PDI Super Sani-Cloth Germicidal Disposable Wipe (EPA registration # 9480-4). The robustness studies were designed to simulate 3 years of multiple-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.