SPECIAL 510(k): Device Modification
OIR Decision Summary

To: THE FILE **RE:** DOCUMENT NUMBER k162282

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.)

   PTS PANELS CHOL+HDL+GLU Panel Test Strips (k071507)

   PTS PANELS CHOL+HDL Panel Test Strips (k071593)

   Chol +Glu Test Panel (k041750)

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 modifications to the original device:
   a. Wireless communications capability (professional system)
   b. Software solutions capability
   c. Printer connectivity capability
   d. MEMo chip appearance
   e. Battery type
   f. Multiple language software capability
   g. Wired PC Communication
   h. Analyzer dimensions
   i. The addition of validated cleaning and disinfection instructions to the labeling

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

5. **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 modifications. 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 CardioChek Plus Test System is intended for multiple patient use in professional healthcare settings. The CardioChek Home Test System is intended for single-patient use. Disinfection efficacy studies for this device were performed in k140068. The studies were performed by an outside commercial testing laboratory and demonstrated complete inactivation of duck hepatitis B virus (HBV) with the chosen disinfectant, Super Sani-Cloth (EPA Registration #9480-4). In this submission robustness studies were performed and demonstrated that there was no change in functionality, performance of glucose, cholesterol, and HDL,or external materials after 11,000 cleaning and disinfection cycles. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.