SPECIAL 510(k): Device Modification
OIR Decision Summary

To: THE FILE **RE:** DOCUMENT NUMBER K171484

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: hema-screen™ SPECIFIC, K060463.

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 a product name change from hema-screen™ SPECIFIC to hema-screen™ SPECIFIC Gold and the outer dimensions of the test cassette. The test cassette of the hema-screen™ SPECIFIC Gold has a slimmer housing design while the hema-screen™ SPECIFIC test cassette has a rectangular housing design.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and assay methods. The only difference between the subject device, hema-screen™ SPECIFIC Gold, and predicate, hema-screen™ SPECIFIC is the housing design of the test cassette.

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. A Risk Analysis was used to assess the impact of the modifications on the device and its components. A Risk Analysis was performed following the Failure Modes and Effects Analysis (FMEA) Analysis procedure. A comparison study with fecal test samples was conducted between the predicate (hema-screen™ SPECIFIC) versus the candidate device (hema-screen™ SPECIFIC Gold). Study results showed no impact on device performance. The hema-screen™ SPECIFIC Gold is as safe and effective as the predicate device, hema-screen™ SPECIFIC.

   b) Based on the Risk Analysis, an identification of the verification and/or validation required, including methods or tests used and acceptance criteria was applied and found to be satisfactory. No safety risks were introduced. Descriptions of verification and validation activities were provided for the hema-screen™ SPECIFIC Gold. Comparison results between hema-screen™ SPECIFIC Gold and hema-screen™ SPECIFIC were also provided.

   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.