SPECIAL 510(k): Device Modification
OIR Decision Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER K163554

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™ ER, K102664.

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 product name change from hema-screen™ ER to hema-screen ER XCEL™ Enhanced Readability Fecal Occult Blood Test because of the addition of a GRID design patient sampling slide pack for optional use. GRID and non-GRID patient sampling slides are available for patient sampling.

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 GRID and non-GRID is the surface area of the circles and number of circles on the cardboard sleeve. The outer cardboard in the GRID design contains smaller surface area (small circles) to help prevent oversampling and ease of patient use.

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. Immunostics performed Risk Analysis following the Failure Modes and Effects Analysis (FMEA) Analysis procedure. A comparison study with fecal test samples was conducted between the non-GRID vs. GRID slides. Study results showed no impact on device performance. The hema-screen ER XCEL™ Enhanced Readability Fecal Occult Blood Test is as safe and effective as the predicate device, hema-screen™ ER.

   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 patient or safety risks are introduced. Descriptions of verification and validation activities were provided for the hema-screen ER XCEL™ Enhanced Readability Fecal Occult Blood Test. Test results for hema-screen ER XCEL™ Enhanced Readability fecal occult blood test compared to hema-screen™ ER 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.