SPECIAL 510(k): Device Modification
OIR Decision Summary

To: THE FILE **RE:** DOCUMENT NUMBER K160885

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:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.

   HemosIL D-Dimer HS; K151534

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.

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 modification of the Limit of Detection value to comply with the current guideline document CLSI EP17-A2.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics and the assay Limit of Detection value:

   The Limit of Detection value has been updated from 21 ng/mL to 137 ng/mL for the HemosIL D-dimer HS assay. HemosIL D-dimer HS and the currently marketed device share the same Intended Use/Indications for Use, same principles of operation, same formulation and same performance 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

      The Risk Analysis for the proposed change was conducted in accordance with ISO 14971. It was concluded that the proposed change does not pose any additional risks and there is no impact on the safety or effectiveness of the product.

   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

      Based on the Risk Analysis, and the fact that there are no other changes or newly identified risks caused by the proposed change, additional verification/validation activities are not required.

The labeling for the 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 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 device.