SPECIAL 510(k): Device Modification
OIR Decision Memorandum

To: THE FILE RE: DOCUMENT NUMBER K151534

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, K070927.

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 the addition of general information from peer-reviewed literature regarding the association of patient age with D-Dimer levels to the HemosIL D-Dimer HS product insert sheet.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, sample type, instrument, and performance claims.

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 was conducted in accordance with ISO 14971, Medical Devices—Application of Risk Management to Medical Devices, and following the manufacturer's internal risk management procedure. There is no additional risk associated with the changes (page 6 of Section 10, Risk Management Report).
   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. No verification and/or validation activities were required (page 6 of Section 10, Risk Management Report).

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.