

SPECIAL 510(k): Device Modification
OIR Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER: K133005

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II device 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 von Willebrand Activity, k040843).
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 labeling for the previously cleared HemosIL von Willebrand Activity (k040843). The modification consists of the addition of the following text to the limitations/interfering substances section of the product's insert sheet: "*The presence of increased level of Human Anti-Bovine IgG antibodies (HABIA) in some patients may lead to an overestimation of results. The results of this assay should therefore be used with other information, including the clinical context, in forming a diagnosis. Do not use this assay as the sole basis for therapy decisions.*"
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics. The difference is the addition of the interference warning to the product's insert sheet. (see page 11 of 17 of K133005/S001)
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. (*Not applicable*)
 - 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. (*Not applicable*)
 - c) A declaration of conformity with design controls. The declaration of conformity should include:
 - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met. (*Not applicable*)
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. (*Not applicable*)
6. A **Truthful and Accurate Statement** (page 35 of 58), a **510(k) Statement** (page 17 of 17 of K133005/S001) and the **Indications for Use Enclosure** (page 14 of 17 of K133005/S001).

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.