

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

To: THE FILE

RE: DOCUMENT NUMBER

k130962

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 Submitters previously cleared device: CBC-5D Plus Retics, k072096.
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, and package labeling.
3. A description of the device **MODIFICATION(S)**, including device description and package insert in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
This change was to change the tri-level Hematology control to reticulocyte parameters only, instead of the combining with complete blood count parameters in the original version.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and stability.
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 according to R&D Systems Risk Analysis and Management Procedure compliant with ISO 14971. The risk analysis for the predicate was performed using failure mode and effects analysis (FMEA) method (page 37 of 59.)
 - 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 (page 37 of 59).
 - 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 (page 53 of 59), and
 - 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 (page 53 of 59).
6. A **Truthful and Accurate Statement** (page 3 of 59), a **510(k) Summary** (page 35 of 59) and the **Indications for Use Enclosure** (page 59 of 59).

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 device.