SPECIAL 510(k): Device Modification
OIR Decision Summary

To: THE FILE **RE:** DOCUMENT NUMBER K171664

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: VARIANT™nbs Sickle Cell Program, K080911.

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 a the addition of HbReview Software and a product name change from VARIANT™nbs Sickle Cell Program to Hemoglobin Variants System on Newborn Screening System with GDM and HbReview Software.

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 the subject device and predicate is the addition of the HbReview Software which offers central site result collection and review capabilities for results transmitted from the GDM (Genetic Disease Management) software. When compared to the predicate device labeling, the modified device includes instructions for transmitting run data using the Genetic Data Management (GDM) 3.1.5 Software for the Newborn Hemoglobin System™ (NHS), and an additional instruction manual for the HbReview Software that describes functionality, usability and interface requirements and limitations.

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. Risk Analysis was performed following Risk Management Procedure; SOP 2013. Software updates were reviewed using Failure Mode Effects Analysis to identify potential risks (Appendix A), ISO 14971 and FDA guidance for the Content of Premarket Submission for Software Contained in Medical Devices. A high level risk analysis and a detailed software risk analysis with mitigation information were provided in the Verification and Validation Report and Software Hazard Analysis Report (Appendix A). In conclusion, no patient or safety risks are introduced.

   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria was applied and found to be satisfactory. No safety risks were introduced. Descriptions of the verification and validation activities were provided for the Hemoglobin Variants System. System level test protocols, including pass/fail criteria, and test results for newborn screening hemoglobin assays 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.