

SPECIAL 510(k): Device Modification  
OIR Decision Summary

To: THE FILE

RE: DOCUMENT NUMBER K161364

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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: BinaxNOW® G6PD Test, K080003.
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 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** expansion of the storage temperature range. In addition, modifications were made to the labeling, including package insert and outer box labeling, to reflect the changes.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and stability. The difference is the expanded storage temperature from 15–30°C to 2–30°C.
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. A risk assessment of expanding the storage temperature range from 15–30°C to 2–30°C was conducted and documented per Quality System requirements. Failure Modes and Effects Analysis (FMEA) was used to assess risk. The modification made to the BinaxNOW® G6PD Test does not affect the assay procedure and this change does not impact the performance of the test or its safety and effectiveness. An update to the product labeling was required to reflect this expanded storage temperature range.
  - 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. To support the expanded storage temperature range, real-time stability data on three lots of test devices and three lots of Reagent A were collected throughout the claimed shelf life at the extremes of storage temperature, 2–8°C and 30°C. The results support BinaxNOW® G6PD Test shelf life of 24 months when stored at 2–30°C.

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.