

SPECIAL 510(k): Device Modification
OIR Decision Summary

To: THE FILE

RE: DOCUMENT NUMBER K153165

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. (For a pre-amendments device, a statement to this effect has been provided.) NEPHROCHECK Test System, DEN130031.
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. Labeling changes to the NEPHROCHECK® Test instructions for use to add myoglobin as a substance that does not exhibit interference with the AKIRISK™ Score in the "Interfering Substances" section of the Performance Characteristics section.
 - b. Labeling changes to the "Storage and Handling Requirements" section of the NEPHROCHECK® Test instructions for use to change the storage conditions to 2-8°C and extend the shelf life stability claim for the NEPHROCHECK® Test System.
 - c. Addition of a second supplier for anti-IGFBP-7 antibody.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics and performance characteristics.
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
 - 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

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 pre-amendment) device.