SPECIAL 510(k): Device Modification
OIR Decision Summary

To: THE FILE **RE:** DOCUMENT NUMBER K141999

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): ADVIA Centaur TSH.

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. **ADVIA Centaur TSH (k910981).**
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. Changing the measuring range of the TSH assay from 0.01-150 µIU/mL to 0.05 - 150 µIU/mL.
   B. Labeling change to the ADVIA Centaur TSH assay to reflect new LoQ result.
   C. Modifications in the ADVIA Centaur XPT Immunoassay System, including:
      i. Remanufacture of PC boards and cables with RoHS compliant (lead-free) components, and the replacement of fire retardant substances applied to the instrument covers.
      ii. Replace the Sun-based PC used for the User Interface and Real-Time application.
      iii. Updated User Interface application.
      iv. Eliminate monthly cleaning procedure.
      v. Change the mounting location of the reagent refrigeration hardware.
      vi. Additional 2D barcode capability.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and performance studies of the ADVIA Centaur TSH assay.
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 preamendment) device.