SPECIAL 510(k): Device Modification
ODE Review Memorandum

To: THE FILE
Re: K 041812 Roche Precinorm® PUC and Precipath® PUC
Date: July 21,2004

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 preamendments device, a statement to this effect has been provided.)

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.

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 to: Add Immunoglobulin A and Immunoglobulin M constituents to Precipath® PUC. Modify corresponding labeling changes by the (addition of IgA and IgM values to value sheet), and edit labeling by removal of asterisks and footnotes from value sheet.

   Comparison Information (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, and physical characteristics.

Device description and comparison

Characteristic	**Precinorm® PUC / Precipath® PUC (Predicate Device, K040280)**	**Precinorm® PUC / Precipath® PUC (Modified Device, K041812)**
Intended Use	For use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.	Same
Format	Liquid ready-for-use control based on a buffered aqueous solution. Concentrations fo control components have been adjusted to represent normal and pathological ranges.	Same
Stability	Unopened	Same

	Stable at 2-8 °C until expiration date <u>Opened</u> Stable at 2-8 °C for 4 weeks.	
Constituent analytes with Assigned Values	<u>Precinorm</u> • Albumin • Creatinine • Total Protein <u>Precipath</u> • Albumin • Creatinine • Total Protein	<u>Precinorm</u> • Albumin • Creatinine • Total Protein <u>Precipath</u> • Albumin • Creatinine • Total Protein • Immunoglobulin A • Immunoglobulin M

4. 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
   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, 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.

5. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

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.

Reviewer Comments:

The Roche Precinorm® PUC and Precipath® PUC Controls have been modified to Apply these 510(k) cleared reagents to Roche / Hitachi MODULAR analyzers and COBAS INTEGRA analyzer systems in accordance with Roche Diagnostics replacement reagent policy.

Modification of the Precinorm® PUC and Precipath® PUC Controls does not affect the intended use of indications for use as described in the labeling, nor does it alter the fundamental scientific technology of the device.

Regulatory Classification

MULTI-ANALYTE CONTROLS, ALL KINDS (ASSAYED AND UNASSAYED)			
862.1660	JJY	I	Panel 75