

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER K073277

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.)
Roche C-Reactive Protein (Latex)
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).
The intended use has been modified to include new members of the instrument family as is allowed by the Replacement Reagent Policy.
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:
 - *Change of calibrator and controls. The calibrator and controls were previously cleared for use with C-RP (K011226 and K003400, K012371, respectively)*
 - *Validation of the high end of the measuring range up to 200 mg/L and up to 250 mg/L for the Roche/Hitachi cobas c 501 and c 311.*
 - *More specific Lipemia interference (L-index) data provided based on testing with Intralipid*
 - *The Limitations section of the COBAS Integra labeling was modified to include information about HAMA, monoclonal gammopathy, and additional testing of a common drug panel.*
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics.
The 510(k) Summary outlined the similarities and differences to the predicate including. Method comparison demonstrated that the COBAS Integra 700 CRP Latex using the CRP T Standard versus the COBAS Integra 700 CRP Latex with the Cfas calibrator yielded linear regression $y = 0.996x - 0.60$ mg/L. Values ranged from 0.62 to 362 mg/L.
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 summary of Risk Analysis was provided which included identification of possible hazards, modes of controls to minimize hazards and the acceptance criteria for those controls. The specifications were met.
 - 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.
Summary of the verification of assay performance characteristics was provided.
 - 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.
Provided in the electronic submission, and a second signed sheet was provided in the supplement.

6. A Truthful and Accurate Statement, a 510(k) Summary and the Indications for Use Enclosure.

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.