

SPECIAL 510(k): Device Modification ODE Review Memorandum

To: THE FILE

RE: DOCUMENT NUMBER

K040431

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. **Roche Diagnostics Tina-quant IgM assay previously cleared K955908**

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**.
The modifications to the assay include:
 - Changes in reagent formulation
 - Additional application with increases sensitivity at the low end of the measuring range
 - Changing the name of the assay to Tina-quant IgM Gen.2

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, additional expected value ranges for children 0-19 years and change in measuring range as follows:

Tina-quant IgM (K955908)	Tina-quant IgM Gen.2
Roche/Hitachi 902 30-490 mg/dL Roche/Hitachi 904/911/912/917/Modular 25-650 mg/dL 3-5362 mg/dL with rerun	Roche/Hitachi 902 25-650 mg/dL Roche/Hitachi 904/911/912/917/Modular 25-650 mg/dL 3-3660 mg/dL with rerun Sensitive Application Roche/Hitachi 902 4-150 mg/dL Roche/Hitachi 904/911/912/917/Modular 4-150 mg/dL 1-450 mg/dL with rerun
Expected values Adults:40-230 mg/dL	Expected values Adults: 40-230 mg/dL Additional ranges for children 0-19 years

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- *FMEA (Failure mode and effects analysis) see section IV, p.25*

- 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* (see section IV pages 26-27)
- c) A declaration of conformity with design controls (see section IV, p 28). 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.

6. 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.

Comments

The sponsor provided information on why modifications were made in reagent formulation, the utility of the sensitive application and why sample stability changed in the modified devices.

The reagent modifications were made to reduce the hook effect and interference caused by lipemic samples. The changes in assay performance due to these modifications were validated and acceptance criteria for assay performance were met.

The sensitive application is used to measure analytes below the expected range. Decreased levels of IgA and IgM can be seen in congenital and acquired deficiency diseases, protein-losing gastroenteropathies, and burns.

The sample stabilities were updated to reflect the latest recommendations from WHO. The acceptable anticoagulants did not change. The labeling was updated to include the cationic component of each anticoagulant instead of only the anticoagulant name.

Reference values for pediatric were derived from CRM 470 Protein Standardization. A reference regarding pediatric ranges was provided. The need for a laboratory to investigate transferability of the expected values to ones own patient population is stated in the package insert.