SPECIAL 510(k): Device Modification
Decision Summary

To: THE FILE **RE:** DOCUMENT NUMBER K120572

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II device requiring 510(k). The following items are present and acceptable

1. The name and 510(k) number of the SUBMITTER'S previously cleared device:

   Trade Name:
   BioPlex™ 2200 ToRC IgG Kit
   BioPlex™ 2200 ToRC IgG Calibrator Set
   BioPlex™ 2200 ToRC IgG Control Set

   510(k) number: K080008

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.

3. A description of the device **MODIFICATION(S).** The modification presented in this 510(k) is a change in the frequency of QC testing recommendations specified in the device labeling. The change was from QC testing for each reagent pack and once per day to QC at least once per day and with each new reagent pack lot. The **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   Other minor changes in the labeling were:
   - Change BioPlex Trademark from TM to ®
   - Remove ProClin Trademark
   - Add "≤" symbol for ProClin and sodium benzoate concentrations

   Revise the hazardous symbol in Precautions/Warning section in compliance with new EU regulation 2008/1272/EC and Global Harmonized System (GHS)

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

   Similarities

Feature	Predicate device	Modified Device
Intended Use/ Indications for Use	BioPlex® 2200 ToRC IgG Kit The BioPlex 2200 ToRC IgG kit is a multiplex flow immunoassay intended for the quantitative detection of IgG antibodies to *Toxoplasma gondii (T.gondii)* and Rubella, and the qualitative detection of IgG antibodies to Cytomegalovirus (CMV) in human serum and EDTA or heparinized plasma.	Same

	The ToRC IgG kit is intended for use with the Bio-Rad BioPlex 2200 System. This kit is intended as an aid in the determination of serological status to *T. gondii,* Rubella and CMV. This kit is not intended for use in screening blood or plasma donors. Performance characteristics for *T. gondii* and Rubella have not been evaluated in immunocompromised or immunosuppressed individuals. Performance characteristics for CMV have not been evaluated in immunosuppressed or organ transplant individuals. Performance characteristics of this kit have not been established for use in neonatal screening or for use at a point of care. BioPlex® 2200 ToRC IgG Calibrator Set The BioPlex 2200 ToRC IgG Calibrator Set is intended for the calibration of the BioPlex 2200 ToRC IgG Reagent Pack. BioPlex® 2200 ToRC IgG Control Set The BioPlex 2200 ToRC IgG Control Set is intended for use as an assayed quality control to monitor the overall performance of the BioPlex 2200 Instrument and BioPlex ToRC IgG Reagent Pack in the clinical laboratory. The performace of the BioPlex 2200 ToRC IgG Control Set has not been established with any other *Toxoplasma gondii,* Rubella or Cytomegalovirus (CMV) IgG antibody assays.	
Device Components	Reagent Pack, Negative control, Multi- Analyte Positive controls and Multiple Calibrators	Same
Technical Specifications	Analytical and Clinical Performance Characteristics	Same
Fundamental Scientific Technology	Multiplex flow immunoassay	Same

Differences

Feature	Predicate device	Modified Device
Frequency of Reagent Pack QC Testing	QC once per pack and per day	QC once per day and per new reagent pack lot

5. **Design Control Activities Summary**:

a) Risk Analysis:
A Failure Mode and Effect Analysis (FMEA) method was used to facilitate, capture, and quantify the potential impact of a Low Signal Pack (LSP) occurrence. For the FMEA analysis, the severity of consequences for failure of the ToRC IgG assay to detect toxoplasmosis, rubella, and cytomegalovirus IgG was determined on an analyte by analyte basis using 21 CFR 860, ISO: 14971 (2009) Annex H, and IVDD (98/79/EC). Additionally, the probability of an assay failure occurring, the likelihood that these assay failures would be detected, and the potential misuse of the ToRC IgG assay were considered as part of the risk analysis.

The Residual Risk acceptability criteria (RPN score) was established at ≤ 19 for low level of concern according to the submitter's FMEA risk management plan. The manufacturer showed that, for all analytes measured, the RPN score ranged from 9-16, which represents a low level of concern and does not require additional mitigation activity.

Furthermore, the sponsor implemented additional risk control measures by improving the manufacturing process or environment with regards to minimizing contamination during manufacturing of the kit components.

b) Verification and Validation activities:
The QC data collected from the initial development verification and clinical validation studies for the ToRC IgG Assay show that no incidence of LSP was observed in the assay formulation.
In addition to the verification and validation studies, the manufacturer conducted studies to investigate the effects of bacterial and mold contaminants on the performance of the ToRC IgG assay. These studies were conducted by spiking the BioPlex 2200 ToRC IgG kit with mold and bacterial filtrates at extreme concentrations. The percent recovery of the Positive QC Control was within 90-120%. This is within the manufacturer's pre-established acceptance range. Additionally, the QC control values reported in the spiked samples fell within the pre-established range for all analytes tested in the ToRC IgG assay. These results indicate that the ToRC IgG assay is not significantly affected by challenge with microbial contaminants.

c) Declaration of Conformity
A "Declaration of Conformity" statement was submitted duly signed by the responsible individuals. The statements indicate that;
i) 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) 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.

In conclusion, based on both the results of the verification/validation studies and the risk management report, the modified QC procedure fulfills the requirements of the specifications of the

design control process. This indicates that this modification of QC testing frequency provides an assay performance that is substantially equivalent to the current cleared kit.

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 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 device.