

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

To: THE FILE

RE: DOCUMENT NUMBER K111072

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:

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

Trade Name:

BioPlex™ 2200 MMRV IgG Kit

BioPlex™ 2200 MMRV IgG Calibrator Set

BioPlex™ 2200 MMRV IgG Control Set

510(k) number: K091616

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED**. There is a labeling change to alter the frequency of QC testing from once per pack and per day to once per day or per new reagent pack lot. This labeling change does not affect the intended use.
3. The modification presented in this 510(k) is a change in the frequency of the QC testing recommendations specified in the labeling. The **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
4. Comparison Information (similarities and differences)

Similarities

Feature	Predicate device	Modified Device
Intended Use/ Indications for Use	<p>The BioPlex® 2200 MMRV IgG kit is a multiplex flow immunoassay intended for the qualitative detection of IgG antibodies to Measles, Mumps, Rubella and Varicella-zoster virus (VZV) in human serum and EDTA or heparinized plasma.</p> <p>The BioPlex 2200 MMRV IgG kit is intended for use with the Bio-Rad BioPlex 2200 System.</p> <p>This kit is intended as an aid in the determination of serological status to Measles, Mumps, Rubella, and VZV. This kit is not intended for use in screening blood or plasma donors.</p> <p>The performance of this assay has not been established for use in neonatal, pediatrics and immunocompromised patients, or for use at point of care facilities.</p>	Same
Device Components	Reagent Pack, Negative control,	Same

	Multi- Analyte Positive controls and Multiple Calibrators	
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 or per new reagent pack lot

5. Design Control Activities Summary

a) Risk Analysis:

A Failure Modes and Effects Analysis was used to facilitate, capture and quantify potential impacts of the Low Signal Pack (LSP) phenomenon. The severity of effects for each of the assays was evaluated using 21 CFR 860 and IVDD (98/79/EC). Additionally potential misuse of the MMRV IgG product was considered during the risk analysis.

b) Verification and Validation activities:

It was determined that proteases from mold and bacteria spiked into the reagent can cause low signals during the development phase of the product. Additional verification and validation studies were conducted by spiking the BioPlex 2200 MMRV IgG kit at room temperature (25 °C) with mold and bacterial filtrates (at 1:25, 1:50, 1:100 and 1:500 levels - v/v). The percent recovery ratios of the QC controls were within the 80%-120% and the negative controls were within the specified range as per the product specifications.

The results indicated that the assays (Measles, Mumps, Rubella or VZV IgG) in the MMRV IgG Kit were not significantly affected by the microbial contaminants.

The Residual Risk acceptability criteria (RPN score) was established at < 19 for low level of concern according to the submitter's Risk Management Plan. It was determined that for each of the assays the RPN score was within 9-12, which is considered a low level of concern and hence does not require any additional mitigation activity.

c) Declaration of Conformity

Two "Declaration of Conformity" statements were 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.

Based on the conclusion of the risk management report, the modified QC procedure fulfills the requirements of the specifications of the design control process. Therefore, the performance of the modified QC test frequency is substantially equivalent to the current cleared kit.

6. A Truthful and Accurate Statement, a 510(k) Summary or Statement 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 device.