K964687

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510(k) Summary of Safety and Effectiveness for the Behring N Latex CRP mono Reagent

1. **Manufacturer Name, Address, phone number, contact name and date of preparation:**

Manufacturer: Behringwerke AG,
Postfach 1140
35001 Marburg
Germany

Distributor: Behring Diagnostics Inc.
151 University Avenue
Westwood, MA 02090
617 - 320 - 3153
Contact name: Laura LeBarron

Date of preparation: September 11, 1996

2. **Device name/Classification:**

In vitro diagnostic reagents for the quantitative determination of C-reactive protein (CRP) Class II (866.5270).

3. **Identification of the legally marketed device to which the submitter claims equivalence:**

The Behringwerke N Latex CRP mono Reagent (K962523)

4. **Proposed Device Description:**

The proposed test reagent (N Latex CRP mono Reagent) is an *in vitro* diagnostic reagent intended to be used together with the Behring Nephelometer Systems in the quantitative determination of C-reactive protein in human serum or plasma.

In the proposed product polystyrene particles coated with mouse monoclonal antibodies to C-reactive protein are agglutinated when mixed with samples containing C-reactive proteins. The intensity of the resulting scattered light in the nephelometer is dependent upon the C-reactive protein content so that, by comparison to standards of known concentration the C-reactive protein content of a sample can be determined.

5. Proposed Device Intended Use:

The proposed test reagent (N Latex CRP mono Reagent) is an *in vitro* diagnostic reagent intended to be used together with the Behring Nephelometer Systems in the quantitative determination of C-reactive protein in human serum or plasma.

6. Medical device to which equivalence is claimed and comparison information:

The N Latex CRP mono Reagent for use with serum or plasma samples is substantially equivalent in intended use and results obtained to the N Latex CRP mono Reagent (K962523) for use with serum samples. The N Latex CRP mono Reagent is intended to be used for the quantitative determination of C-reactive protein in human serum or plasma by particle enhanced nephelometry.

7. Proposed Device Performance Characteristics:

Correlation

Results of comparative serum versus plasma studies for both EDTA and heparin plasma samples using the N Latex CRP mono reagent gave correlation coefficients of 0.998 and 0.999, respectively, y-intercepts of 0.166 and 0.79, respectively, and slopes of 0.979 and 0.989, respectively.