K962523

JUL 10 1996

Attachment 1

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

1. Manufacturer Name, Adress, 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 - 3023
Contact name: Kathleen Dray-Lyons

date of preparation: May 29, 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 (K860894)

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.

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.

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

The N Latex CRP mono Reagent is substantially equivalent in intended use and results obtained to N Latex CRP. The N CRP Reagent, like the proposed product is intended to be used for the quantitative determination of C-reactive protein in human serum by particle enhanced nephelometry

The N Latex CRP mono Reagent differs from the N Latex CRP in that the N Latex CRP mono Reagent is calibrated using a lot independent standard, whereas the N CRP Reagent is calibrated using a lot dependent standard (included in the kit). Also, the N Latex CRP mono Reagent is a liquid reagent consisting of polystyrene particles coated with mouse monoclonal antibodies to CRP, where as the N CRP Reagent is a lyphilized reagent containing polystyrene particles which are coated with antibodies of the γ-fraction from a specific rabbit anti-human-CRP serum. Additionally, the N Latex CRP mono Reagent is designed to measure CRP concentrations within an overall range of approx. 0.175 - 1100 mg/l , whereas, the N Latex CRP measuring range is approx. 0.625 - 800 mg/l. A copy of the N Latex CRP Reagent package insert is included in this submission.

7. Proposed Device Performance Characteristics:

Correlation

Results of comparative studies using the N Latex CRP mono Reagent and the the N Latex CRP test kit for 71 serum samples gave a correlation coefficient of 0.98 and a y-intersept of 1.43, and a slope of 0.95.

Precision

N Latex CRP mono Reagent was used to measure 3 different CRP concentrations (approx. 15, 25 and 60 mg/l) and yielded coefficients of variation of 4.0%, 2.3% and 4.4% for the intra-assay precision (n = 20).
Five CRP concentrations (approx. 10, 15, 25, 45 and 60 mg/l) were used to determine the inter-assay reproducibility (n = 10) and here the coefficients of variation ranged from 2.6 % to 5.7 %.