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Summary of Safety & Effectiveness
IMMAGE™ Immunochemistry System Rheumatoid Factor (RF) Reagent

1.0 **Submitted By:**

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2.0 **Date Submitted:**

05 Aug-1996

3.0 **Device Name(s):**

3.1 **Proprietary Names**

IMMAGE™ Immunochemistry System Rheumatoid Factor (RF) Reagent

3.2 **Classification Names**

Rheumatoid factor immunological test system(21 CFR 866.5775)

4.0 **Predicate Device(s):**

Behring Diagnostics N Latex RF, K942328

5.0 **Description:**

The IMMAGE Systems Rheumatoid Factor (RF) Reagent is designed for optimal performance on the IMMAGE Immunochemistry System. It is intended for use in the quantitative determination of human rheumatoid factor concentrations in human serum and plasma samples.

6.0 **Intended Use:**

The IMMAGE Immunochemistry Systems Rheumatoid Factor (RF) reagent, in conjunction with Beckman Cal 5 Plus, is intended for use in the quantitative determination of human rheumatoid factor concentrations in human serum and plasma samples by rate nephelometry. This assay is designed for use with the IMMAGE Immunochemistry System.

7.0 Comparison to Predicate(s):

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

Reagent	Aspect/Characteristic	Comments
SIMILARITIES		
IMMAGE System RF Reagent	Intended use	Same as Behring N Latex RF
IMMAGE System RF Reagent	Nephelometric methodology	Same as Behring N Latex RF
IMMAGE System RF Reagent	Latex particle technology	Same as Behring N Latex RF
DIFFERENCES		
IMMAGE System RF Reagent	Form of reagent	IMMAGE RF is a liquid stable reagent, while Behring N Latex RF is lyophilized.
IMMAGE System RF Reagent	Stability	IMMAGE RF reagent is stable for 14 days once opened, properly stored, while Behring N Latex RF reagent is stable for one week following reconstitution

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, and imprecision experiments that relate results obtained from the Behring N Latex RF Reagent to the IMMAGE System RF Reagent.

Method Comparison Study Results
IMMAGE RF Reagent vs. Behring N Latex RF Reagent

Analyte	Slope	Intercept	r	Predicate
IMMAGE RF	1.055	0.41	0.940	Behring N Latex RF

Stability Study Results

Reagent	Product Claim
IMMAGE RF	24 months shelf-life 14 day open container 14 day calibration

Estimated Within-Run Imprecision

MATERIAL	MEAN (IU/mL)	SD (IU/mL)	%CV	Number of Results
IMMAGE System RF Reagent				
Level 1	124	2.5	2.1	80
Level 2	299	4.5	1.5	80
Level 3	637	12.4	1.9	80

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.