

K964842

BECKMAN

Summary of Safety & Effectiveness IMMAGE™ Immunochemistry System Complement C3 (C3) and Complement C4 (C4) Reagents

1.0 **Submitted By:**

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2.0 **Date Submitted:**

26 November 1996

3.0 **Device Name(s):**

3.1 **Proprietary Names**

IMMAGE™ Immunochemistry System Complement C3 (C3) Reagent
IMMAGE™ Immunochemistry System Complement C4 (C4) Reagent

3.2 **Classification Name**

Complement components) immunological test system (21 CFR § 866.5240)

4.0 **Predicate Device(s):**

IMMAGE System Reagent	Predicate	Manufacturer	Docket Number
Complement C3 (C3) Reagent	Immunochemistry Systems Complement C3 Reagent	Beckman Instruments Inc. *	K771603
Complement C4 (C4) Reagent	Immunochemistry Systems Complement C4 Reagent	Beckman Instruments Inc.*	K780913

Beckman Instruments, Inc.

5.0 Description:

The IMMAGE Immunochemistry System C3 and C4 Reagents in conjunction with Beckman Calibrator 1, are intended for use in the quantitative determination of Complement C3 and Complement C4 concentrations respectively in human serum samples on Beckman's IMMAGE Immunochemistry System.

6.0 Intended Use:

The IMMAGE Immunochemistry System Complement C3 (C3) Reagent, when used in conjunction with Beckman IMMAGE™ Immunochemistry Systems and Beckman Calibrator 1, is intended for the quantitative determination of Complement C3 by rate nephelometry.

The IMMAGE Immunochemistry System Complement C4 (C4) Reagent, when used in conjunction with Beckman IMMAGE™ Immunochemistry Systems and Beckman Calibrator 1, is intended for the quantitative determination of Complement C4 by rate nephelometry.

7.0 **Comparison to Predicate(s):**

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

C3 Similarities With The Predicate

Reagent	Aspect/Characteristic	Comments
IMAGE System C3 Reagent	Assay method - rate nephelometry	Same as Beckman's Immunochemistry Systems Complement C3 reagent on the Array System
	Sample / reagent ratios	
	Antibody	

C4 Similarities With The Predicate

Reagent	Aspect/Characteristic	Comments
IMAGE System C4 Reagent	Assay method - rate nephelometry	Same as Beckman's Immunochemistry Systems Complement C4 reagent on the Array System
	Sample / reagent ratios	
	Measuring Range: Initial 10 - 130 mg/dL Extended 10 - 4,680 mg/dL	
	Antibody	

C3 Differences From The Predicate

Reagent	Aspect/Characteristic	Comments
IMAGE System C3 Reagent	Reaction Temperature	IMAGE System C3 assays run at 37°C and the predicate runs at 26.7°C.
IMAGE System C3 Reagent	Reagent Container	IMAGE reagent is stored in a plastic cartridge and predicate reagent is stored in glass vials.

C4 Differences From The Predicate

Reagent	Aspect/Characteristic	Comments
IMAGE System C4 Reagent	Reaction Temperature	IMAGE System C4 assays run at 37°C and the predicate runs at 26.7°C.
IMAGE System C4 Reagent	Reagent Container	IMAGE reagent is stored in a plastic cartridge and predicate reagent is stored in glass vials.

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 Beckman Reagents to the IMMAGE System Reagents.

Method Comparison Study Results
 IMMAGE Complement C3 (C3) and Complement C4 (C4) Reagents

Analyte	Sample Type	Slope	Intercept	r	n	Predicate Method
Complement C3	serum	0.969	6.18	0.994	100	Complement C3 Reagent on the Array
Complement C4	serum	0.983	-1.48	0.984	124	Complement C4 Reagent on the Array

Stability Study Results

Reagent	Product Claim
IMMAGE C3 & C4	24 month shelf-life 14 day open container stability 14 day calibration stability

Estimated Imprecision

IMMAGE System C3 Reagent Precision Study Results

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision				
Level 1	70.3	1.79	2.5	80
Level 2	106	3.1	2.9	80
Total Precision				
Level 1	70.3	2.09	3.0	80
Level 2	106	3.9	3.6	80

IMMAGE System C4 Reagent Precision Study Results

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision				
Level 1	18.8	0.60	3.2	80
Level 2	42.9	1.45	3.4	80
Level 3	65.5	1.65	2.5	80
Total Precision				
Level 1	18.8	0.65	3.4	80
Level 2	42.9	2.21	5.2	80
Level 3	65.5	2.46	3.7	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.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.

Director

Division of Clinical

Laboratory Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K 96 4842

Device Name: **IMAGE™ Immunochemistry System
Complement C4 (C4) Reagent**

Indications for Use:

The IMAGE Immunochemistry System Complement C4 (C4) Reagent, when used in conjunction with Beckman IMAGE™ Immunochemistry Systems and Beckman Calibrator 1, is intended for the quantitative determination of human complement C4 by rate nephelometry.

21 CFR 866.5240 Complement components immunological test system

(a) Identification. A Complement components immunological test system is a device that consists of the reagents used to measure by immunochemical techniques complement components C_{1q}, C_{1r}, C_{1s}, C₂, C₃, C₄, C₅, C₆, C₇, C₈, and C₉ in serum, other body fluids, and tissues. Complement is a group of serum proteins which destroy infectious agents. Measurements of these proteins aids in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.

(b) Classification. Class II (performance standards).

Peter E. Makin
(Division Sign-Off)
Division of **Clinical Laboratory Devices**
510(k) Number

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(per 21 CFR 801.109)

OR

Over-the-Counter Use _____
Optional Format 1-2-96