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BECKMAN

K974564

Summary of Safety & Effectiveness
IMMAGE™ Immunochemistry System Alpha$_2$-Macroglobulin (AMG) Reagent

FEB 17 1998

1.0 **Submitted By:**

Annette Hellie
Sr. Regulatory Specialist, Product Submissions
Beckman Instruments, Inc.
200 S. Kraemer Blvd., W-337
Brea, California 92822-8000
Telephone: (714) 993-8767
FAX: (714) 961-4457

2.0 **Date Submitted:**

December 4, 1997

3.0 **Device Name(s):**

3.1 **Proprietary Names**

IMMAGE™ Immunochemistry System Alpha$_2$-Macroglobulin (AMG) Reagent

3.2 **Classification Name**

Alpha$_2$-Macroglobulin immunological test system (21 CFR § 866.5620)

4.0 **Predicate Device(s):**

IMMAGE System Reagent	Predicate	Manufacturer	Docket Number
IMMAGE System Alpha$_2$-Macroglobulin(AMG)	Beckman Alpha$_2$-Macroglobulin (AMG)	Beckman Instruments, Inc.	K791340

5.0 **Description:**

The IMMAGE Immunochemistry System AMG Reagent, in conjunction with Beckman Calibrator 2, is intended for use in the quantitative determination of Alpha$_2$-Macroglobulin concentrations on Beckman's IMMAGE Immunochemistry System.

6.0 **Intended Use:**

The IMMAGE Immunochemistry System Alpha$_2$-Macroglobulin (AMG) Reagent, when used in conjunction with Beckman IMMAGE™ Immunochemistry Systems and Beckman Calibrator 2, is intended for the quantitative determination of human Alpha$_2$-Macroglobulin by rate nephelometry.

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 AMG Reagent	Nephelometric methodology	Same as Beckman AMG reagent
	Antibody source (goat)	
DIFFERENCES		
IMMAGE System AMG Reagent	Buffer/Reagent volumes	IMMAGE System uses half of the volumes than are utilized by the Array System for AMG.
	Antibody concentration	IMMAGE AMG has a higher antibody concentration than the Beckman Alpha$_2$-Macroglobulin reagent

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 on the IMMAGE System.

Method Comparison Study Results
IMMAGE Alpha$_2$-Macroglobulin (AMG) Reagent

Analyte	Sample Type	Slope	Intercept	r	n	Predicate Method
IMMAGE AMG Reagent	serum	0.966	1.19	0.994	106	Beckman Array Systems AMG

Stability Study Results

Reagent	Product Claim
IMMAGE AMG	24 month shelf-life 14 day open container stability 14 day calibration stability

Estimated Imprecision

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision				
Level 1	44.6	1.32	3.0	80
Level 2	186	4.4	2.4	80
Level 3	300	9.2	3.1	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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Annie Hellie
Senior Regulatory Specialist
Beckman Instruments, Inc.
200 S. Kraemer Blvd., W-337
Brea, CA 92822-8000

FEB 17 1998

Re: K974564
Trade Name: Immage Immunochemistry System Alpha(2)-Macroglobulin (AMG) Reagent
Regulatory Class: II
Product Code: DEB 82
Dated: December 04, 1997
Received: December 05, 1997

Dear Ms. Hellie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 Gutman

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): K974564

Device Name: **IMMAGE™ Immunochemistry System**
Alpha$_2$-Macroglobulin (AMG) Reagent

Indications for Use:

Intended Use:

The IMMAGE Immunochemistry System Alpha$_2$-Macroglobulin (AMG) Reagent, when used in conjunction with Beckman IMMAGE™ Immunochemistry Systems and Beckman Calibrator 2, is intended for the quantitative determination of human alpha$_2$-macroglobulin by rate nephelometry.

Clinical Significance:

Measurement of alpha$_2$-macroglobulin may aid in the diagnosis of blood-clotting or clot lysis disorders.

Peter E. Madsen

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974564

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96