NOV 25 1998

K983895

BECKMAN COULTER

Summary of Safety & Effectiveness
Beckman Coulter IMMAGE® Immunochemistry System Beta-2-Microglobulin Reagent

1.0 **Submitted By:**

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200 South Kraemer Blvd., W-104
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2.0 **Date Submitted:**

02 November 1998

3.0 **Device Name(s):**

3.1 **Proprietary Names**

IMMAGE® Immunochemistry System Beta-2-Microglobulin Reagent

3.2 **Classification Name**

(21 CFR §866.5630) Beta-2-Microglobulin immunological test system

4.0 **Predicate Device(s):**

IMMAGE Reagent	Predicate	Manufacturer	Docket Number
IMMAGE System Beta-2-Microglobulin (B2MX)	Beckman Array® Beta-2-Microglobulin (B2M)	Beckman Instruments, Inc.	K940353

5.0 **Description:**

The IMMAGE® Immunochemistry System Beta-2-Microglobulin (B2MX) Reagent is designed for optimal performance on the IMMAGE® Immunochemistry Systems. It is intended for the quantitative determination of beta-2-microglobulin in serum or plasma.

6.0 **Intended Use:**

The IMMAGE® Immunochemistry System Beta-2-Microglobulin (B2MX) Reagent, when used in conjunction with Beckman Coulter's IMMAGE® Immunochemistry Systems and Calibrator 2, is intended for the quantitative determination of human beta-2-microglobulin in serum or plasma by rate nephelometry.

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

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

SIMILARITIES to the PREDICATE

IMMAGE System	Aspect/Characteristic	Comments
IMMAGE System B2MX Reagent	Intended use	Same as Array Beta-2-Microglobulin
	Reaction temperature of 37° C	
	Detection methodology of rate nephelometry	

DIFFERENCES from the PREDICATE

IMMAGE System	Aspect/Characteristic	Comments
IMMAGE System B2MX Reagent	Sample dilution	IMMAGE has on line sample dilution. Array requires off line sample dilution.
	Antibody source	IMMAGE is rabbit (polyclonal). Array is goat (polyclonal).
	Antibody reagent composition	IMMAGE is latex particle bound antibody. Array is soluble antibody.

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 and imprecision experiments.

Method Comparison Study Results

IMMAGE® System Beta-2-Microglobulin (B2MX) Reagent

Analyte	Sample Type	Slope	Intercept (mg/dL)	r	n	Predicate Method
IMMAGE B2MX Reagent	serum	0.979	-0.017	0.996	111	Array 360 Beta-2-Microglobulin

IMMAGE® System Beta-2-Microglobulin (B2MX) Imprecision

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision				
Level 1	0.10	0.010	10.0	80
Level 2	1.84	0.042	2.3	80
Level 3	3.19	0.062	1.9	80
Total Imprecision				
Level 1	0.10	0.010	10.0	80
Level 2	1.84	0.048	2.6	80
Level 3	3.19	0.069	2.2	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

NOV 25 1998

Mr. Richard T. Ross
Staff Regulatory Specialist,
Product Submissions
Beckman Coulter, Inc.
200 South Kraemer Boulevard, W-104
Brea, California 92822-8000

Re: K983895
Trade Name: IMMAGE® Immunochemistry System Beta-2 Microglobulin Reagent
Regulatory Class: II
Product Code: JZG
Dated: November 2, 1998
Received: November 3, 1998

Dear Mr. Ross:

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 legally marketed predicate 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.

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 (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/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): K983895 ~~Not yet assigned~~

Device Name: **IMMAGE® Immunochemistry System**
Beta-2-Microglobulin (B2MX) Reagent

Indications for Use:

The IMMAGE® Immunochemistry System Beta-2-Microglobulin (B2MX) Reagent, when used in conjunction with Beckman Coulter's IMMAGE® Immunochemistry Systems and Calibrator 2, is intended for the quantitative determination of human Beta-2-Microglobulin in serum or plasma by rate nephelometry.

Clinical Significance:

An increase in the concentration of serum beta-2-microglobulin can result from an overproduction of the protein by nucleated cells and/or decreased clearance by the kidneys. Under normal conditions, beta-2-microglobulin passes readily through the glomerular membrane. Levels of beta-2-microglobulin in serum, therefore, are inversely proportional to glomerular filtration rate (GFR). Measurement of Beta-2-Microglobulin in serum or plasma assists in the diagnosis and management of patients with active rheumatoid arthritis and renal disease.

(21 CFR §866.5630) Beta-2-Microglobulin immunological test system

(b) *Classification.* Class II.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maddux

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983895

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