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BECKMAN K973813

Summary of Safety & Effectiveness
IMMAGE™ Immunochemistry System Beta-2-Microglobulin (B2M) Reagent

NOV 20 1997

1.0 **Submitted By:**

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2.0 **Date Submitted:**

October 6, 1997

3.0 **Device Name(s):**

3.1 **Proprietary Names**

IMMAGE™ Immunochemistry System Beta-2-Microglobulin (B2M) Reagent

3.2 **Classification Name**

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

4.0 **Predicate Device(s):**

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

5.0 **Description:**

The IMMAGE Immunochemistry System B2M Reagent in conjunction with Beckman Calibrator 2, is intended for use in the quantitative determination of beta-2-microglobulin concentrations in human serum samples on Beckman's IMMAGE Immunochemistry System.

6.0 **Intended Use:**

The IMMAGE Immunochemistry System Beta-2-Microglobulin (B2M) Reagent, when used in conjunction with Beckman IMMAGE™ Immunochemistry Systems and Beckman Calibrator 2, is intended for the quantitative determination of human beta-2-microglobulin 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 B2M Reagent	Analytic Range	Same as Array System Beta-2-Microglobulin reagent
	Off-line sample dilution	
	Nephelometric methodology	
	Antibody source (goat)	
DIFFERENCES		
IMMAGE System B2M Reagent	Buffer/Reagent volumes	IMMAGE System uses half of the volumes than are utilized by the Array System for B2M.
	Coreagent concentration	IMMAGE B2M has a higher coreagent concentration than the Array Beta-2-Microglobulin 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 from the Beckman Reagent on the Array® 360 System to the IMMAGE System Reagent.

Method Comparison Study Results
IMMAGE Beta-2-Microglobulin (B2M) Reagent

Analyte	Sample Type	Slope	Intercept	r	n	Predicate Method
IMMAGE B2M Reagent	serum	1.019	-0.02	0.997	102	Array 360 System B2M Reagent

Stability Study Results

Reagent	Product Claim
IMMAGE B2M	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	0.34	0.029	8.5	80
Level 2	1.65	0.045	2.7	80
Level 3	3.43	0.099	2.9	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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Annette Hellie
Senior Regulatory Specialist, Product Submissions
Beckman Instruments, Inc.
200 S. Kraemer Boulevard, W-337
Brea, California 92822-8000

NOV 20 1997

Re: K973813
Trade Name: IMMAGE™ Immunochemistry System Beta-2-Microglobulin (B2M) Reagent
Regulatory Class: II
Product Code: JZG
Dated: October 6, 1997
Received: October 7, 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 requirement, 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): **K973813**

Device Name: **IMMAGE™ Immunochemistry System**
Beta-2-Microglobulin (B2M) Reagent

Indications for Use:

The IMMAGE Immunochemistry System Beta-2-Microglobulin (B2M) Reagent, when used in conjunction with Beckman IMMAGE™ Immunochemistry Systems and Beckman Calibrator 2, is intended for the quantitative determination of human beta-2-microglobulin in serum by rate nephelometry.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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