K024210

FEB 2 4 2003

510(k) Summary
IMMAGE® Immunochemistry System
Total Immunoglobulin E Reagent (IGE) Reagent and Calibrator

1.0 **Submitted By:**

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2.0 **Date Submitted:**

December 19, 2002

3.0 **Device Name(s):**

3.1 **Proprietary Names**

IMMAGE® Immunochemistry System Total Immunoglobulin E (IGE) Reagent
IMMAGE® Immunochemistry System IGE Calibrator

3.2 **Classification Name**

Immunoglobulins A, G, M, D, and E test system (21 CFR § 866.5510)
Calibrator (21 CFR § 862.1150)

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
IMMAGE System Total IGE	Access® Total IgE	Beckman Coulter, Inc.	K930984

5.0 **Description:**

Total Immunoglobulin E (IGE) reagent, when used in conjunction with IMMAGE® Immunochemistry Systems and IGE Calibrator, is intended for the quantitative determination of total human immunoglobulin E (IgE) in serum or plasma by rate turbidimetry.

6.0 Intended Use:

Total Immunoglobulin E (IGE) reagent, when used in conjunction with IMMAGE® Immunochemistry Systems and IGE Calibrator, is intended for the quantitative determination of total human immunoglobulin E (IgE) in serum or plasma by rate turbidimetry..

Clinical Significance:

IgE is a member of the immunoglobulin family of proteins that was first described in the 1960's. IgE, like all immunoglobulins, is produced by plasma cells in response to antigenic stimuli. IgE is unique however in certain structural aspects and the role it plays in allergic diseases.

Measurement of total serum IgE is often used as a tool in the diagnosis and management of atopic diseases such as asthma, hay fever, atopic dermatitis and urticaria. It has been used to distinguish atopic from non-atopic individuals presenting allergy-like symptoms. In addition, studies have also shown that increased levels of IgE in cord blood and infants may be predictive of future atopic tendencies.

Normal levels of circulating IgE are extremely low in comparison to other immunoglobulins. Levels of IgE at birth are almost undetectable but increase in non-allergic adults. Elevated levels are commonly seen in cases of allergic diseases, parasitic infections, pulmonary aspergillosis, Wiskott-Aldrich Syndrome, and myeloma.

Serum IgE levels may vary as a result of diet, genetic background, geographical location and other factors. It is therefore recommended that total IgE measurements be used in conjunction with other clinical tests when establishing diagnoses.

7.0 Comparison to Predicate(s):

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

	Similarities	
IMMAGE System Total IGE	Intended Use	Same as Access Total IgE
	Liquid stable reagent	
	Antibody (mouse monoclonal)	
	Differences	
IMMAGE System Total IGE	Methodology	The IMMAGE uses rate nephelometry and the Access uses chemiluminescent immunoassay
	Measuring range	0.25–3000 IU/mL for Access 5.0 – 500 IU/mL (initial dilution) up to 30,000 (extended dilution) for IMMAGE

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, linearity, and imprecision experiments.

Method Comparison Study Results

Analyte	Slope	Intercept	r	n	Predicate Method
IMMAGE Total IGE	1.06	2.75	0.991	125	Access Total IgE

IMMAGE System IGE Estimated Imprecision

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision				
Level 1	16.5	0.97	5.8	80
Level 2	145	7.4	5.1	80
Level 3	383	19.9	5.2	80
Total Imprecision				
Level 1	16.5	1.11	6.7	80
Level 2	145	9.1	6.3	80
Level 3	383	28.1	7.3	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

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Re: k024210
Trade/Device Name: IMMAGE® Immunochemistry System Total Immunoglobulin E Reagent (IGE) Reagent and Calibrator
Regulation Number: 21 CFR § 866.5510
Regulation Name: Immunoglobulins A, G, M, D, and E Test System
Regulatory Class: II
Product Code: DGC
Dated: February 11, 2003
Received: February 12, 2003

Dear Ms. Hellie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K024210

Device Name: **IMMAGE® Immunochemistry System Total Immunoglobulin E Reagent (IGE) Reagent and Calibrator**

Indications for Use:

Total Immunoglobulin E (IGE) reagent, when used in conjunction with IMMAGE® Immunochemistry Systems and IGE Calibrator, is intended for the quantitative determination of total human immunoglobulin E (IgE) in serum or plasma by rate turbidimetry.

(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

J P Rawa for J. Bautista
(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K024210